```
Set      Items   Description
S1       84500   VERTEBR???? OR INTERVERTEBR???? OR INTERSPINAL?? OR INTERS-
             PINOUS?? OR SPINE? ? OR SPINAL OR SPINOUS OR BACKBONE? ? OR B-
             ACK()BONE? ?
S2      640302   BLOCK? ? OR BONEBLOCK? ? OR CHOCK? ? OR WEDGE? ? OR IMPLAN-
             T? ? OR INSERT? ? OR DOWEL? ? OR SPRAG? ? OR SWAGE? ? OR SHIM?
              ? OR SPACER? ? OR SPACING()ELEMENT? ?
S3      905927   INSERT???? OR EMPLAC????? OR ADVANC????? OR INTRODUC????? -
             OR INFIX??? OR EMBED???? OR IMBED???? OR SANDWICH????
S4     1006634   PENETRAT???? OR INTERSPERS???? OR POSITION??? OR (CUT OR C-
             UTS OR CUTTING OR STICK??? OR PUT OR PUTS OR PUTTING)()IN
S5     1260808   SEPARAT???? OR DIVID??? OR DIVERG??? OR DETACH??? OR DISUN-
             IT??? OR DISPLAC??? OR DECOUPL??? OR DISJOIN??? OR DISCONNECT-
             ???
S6      100952   PARTITION??? OR SEGREGAT??? OR (CAM OR CAMS OR CAMMED OR C-
             AMMING OR SPREAD??? OR URGE? ? OR URGING)()APART
S7      930487   ROTAT???? OR TWIRL??? OR TURN??? OR SPIN???? OR REVOLV??? -
             OR SCREW??? OR CIRCUMVOLV??? OR ORIENTAT???? OR GYRAT????
S8     1150386   REMOV???? OR WITHDRAW??? OR DISLODG??? OR EXTIRPAT???? OR -
             EVACUAT???? OR (TAKE? ? OR TAKING OR TOOK)()AWAY
S9     1453465   TWO OR TWIN OR DOUBLE OR SECOND OR BOTH OR PAIR OR 2ND
S10    1215105   PLURAL???? OR SEVERAL OR MULTITUDE OR MULTIPLE OR MULTI OR
             MANY OR ADDITIONAL OR NUMEROUS OR SPARE OR EXTRA OR MORE()THA-
             T()ONE
S11    1278930   METHOD? ?
S12    1118373   SYSTEM? ?
S13     995666   PROCESS??
S14     437226   PROCEDURE? ?
S15     563332   TECHNIQUE? ?
S16      51674   IC=A61B?
S17       2173   S1(10N)S2 AND S11:S15(5N)S3:S4
S18       1800   S17 AND S5:S6 AND S7 AND S8
S19       2173   S17:S18
S20        419   S19 AND S16
S21       2173   S19:S20
S22       1442   S21 AND S9:S10(5N)S2
S23       1142   S22 AND S1(5N)S2
S24       1019   S23 AND S3:S4(5N)S2
S25        324   S24 AND S5:S6(5N)S1:S2
S26        297   S25 AND S7(5N)S1:S2
S27        247   S26 AND S8(5N)S1:S2
S28        232   S27 AND S9:S10(5N)S3:S4
S29        196   S28 AND S1(3N)S2
S30        191   S29 AND S3:S4(3N)S2
S31         97   S30 AND S16
S32        191   S30:S31
S33        169   S32 AND S11:S15(3N)S3:S4
S34        169   IDPAT (sorted in duplicate/non-duplicate order)
? show files
File 348:EUROPEAN PATENTS 1978-2004/Feb W05
         (c) 2004 European Patent Office
File 349:PCT FULLTEXT 1979-2002/UB=20040304,UT=20040226
         (c) 2004 WIPO/Univentio
?
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34/3,K/1 (Item 1 from file: 348)
DIALOG(R)File 348:EUROPEAN PATENTS

01634636
Apparatus and method of inserting spinal implants
Gerat zum Einsetzen von Ruckenwirbelimplantaten
Appareil et procede d' insertion **d'** implants spinaux
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PATENT (CC, No, Kind, Date): EP 1346695 A1 030924 (Basic)
APPLICATION (CC, No, Date): EP 2003014398 960226;
PRIORITY (CC, No, Date): US 396414 950227
DESIGNATED STATES: AT; BE; CH; DE; DK; ES; FR; GB; GR; IE; IT; LI; LU; MC; NL; PT; SE
RELATED PARENT NUMBER(S) - PN (AN):
EP 1129668 (EP 2001114044)
EP 812167 (EP 2096907088)
INTERNATIONAL PATENT CLASS: **A61B-017/17** ; A61F-002/46
ABSTRACT WORD COUNT: 127
NOTE:
Figure number on first page: 1

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Available Text	Language	Update	Word Count
CLAIMS A	(English)	200339	1426
SPEC A	(English)	200339	23327
Total word count - document A			24753
Total word count - document B			0
Total word count - documents A + B			24753

Appareil et procede d' insertion **d'** implants spinaux
INTERNATIONAL PATENT CLASS: **A61B-017/17** ...

...SPECIFICATION the transverse width of the disc space is insufficient to allow for the use of **two implants** , each of which would be large enough to protrude to the required depth into the adjacent **vertebrae** , then a singular and significantly larger **implant** may be placed centrally. With this in mind, and in light of the very detailed...

...in regard to the method of posterior lumbar interbody fusion, a brief discussion of anterior **spinal** interbody fusion with dual **implant** installation will suffice, and the method for installation of a large, singular midline graft will become obvious.
The interspace to be fused is exposed anteriorly. The soft tissues are **withdrawn** and protected to either side, and if necessary, above and below as well. It is **removed** via the drill later.) The surgeon then notes and marks a point midway from side to side anteriorly. He then **inserts** Long Distractor 100 centering it on a point midway between the point just noted and...

...inserted, then its exact duplicate is inserted anteriorly equidistant to the other side of the **spine** . As the barrel portion 106 of Long

Distractor 100 is exactly of the same major diameter as the spinal **implant** I looking coaxially on end, the surgeon can then asses the anticipated side by side...

...implanted.
Preferring to Figures 7C and 7D, a Dual Outer Sleeve 340 consisting of a **pair** of hollow tubes is then **introduced** over the side by side Long Distracters 100 protruding anteriorly from the **spine** . The Dual Outer Sleeve 340 is comprised of two hollow tubular members identical in size **displaced** from each other ideally the sum of the difference between the minor and major diameters of **both** **implants** combined, but not less than that difference for one implant, as it is possible to...

...slightly greater than two times the difference between the major and minor diameters of the **implant** (the sum of **both**) the distance may be considerably greater. Whereas in the preferred embodiment the paired tubular portions...

...may be inclined or declined relative to each other such that they either converge or **diverge** at their proximal ends. The paired tubular portions 348, may be bridged in part or...

...held via a Foot Plate 344 and the prongs 342. Thus, it is possible to **remove** either one, or if desired, both of the Long Distractor rods utilizing Long Distractor puller...

...is then the surgeon's choice to work on one or both sides of the **spine** . As per previous discussion, the surgeon may drill the interspace utilizing the Inner Sleeve 242...

...the Long Distractors in place as per the "Trephine Method".
Tapping, if necessary, and the **insertion** of the **implants** then occurs through the protective Outer Sleeve 340. Once the **implants** have been fully **inserted** , the Outer Sleeve is **removed** .
Having utilized the Drill method, or "Trephine Method", with or without an Inner Sleeve co...

...the interspace, or preferring the ability to directly visualize the cap being used, or the **implant** being **inserted** , may choose to **remove** the Outer Sleeve after the insertion of the first prosthesis to maintain stability, or prior...

...Preferred Embodiment For Method of Anterior Interbody Fusion
As previously described for the posterior lumbar **spine** , alternatively, one can employ the "Trephine Method" as has been described in detail.
As a...

...the preferred embodiment, it is nevertheless within the scope or this invention that one could **remove** the Outer Sleeve as there are no neural structures requiring projection, and **insert** the **implants** directly rather than through the Outer Sleeve.
As yet a further alternative of this method...

...depth into the opposed vertebral bodies is such that it is not possible to place **two** such **implants** side by side, then only a single implant which may be of significantly increased diameter...

...or the "Trephine Method".
Referring to Figures 15-13, a cylindrical embodiment of the spinal

implant of the present invention is shown. In Figure 16 the implant I is shown attached...

...I is shown, installed in the disc space D, between the adjacent vertebrae.

The cylindrical **implant** I comprises a hollow tubular member which in the preferred embodiment is made of an...

...in detail below.

Detailed Description of Alternative Embodiments of Apparatus and Method

When the human **spine** is viewed from the side, it consists of a balanced series of curves, as opposed...

...line when viewed from the side. In both the cervical and lumbar regions of the **spine** , the **vertebrae** relate to each other so as to form curves where the apex of said curves is **displaced** forward within the body, and those segments of the **spine** are said to be in lordosis. In contradistinction, in the thoracic portion of the **spine** , the **vertebrae** relate to each other so as to form a curve where the apex of said curve is **displaced** posteriorly and is said to be in kyphosis. The methods and instrumentation, of the present...

...vertebrae in the correct anatomic lordosis or kyphosis. Where it is possible to approach the **spine** from various angles each of the devices, then has different forms appropriate to that specific...

...of restoring and maintaining lordosis of adjacent vertebrae V from the posterior approach of the **spine** is shown. The Posterior Long Lordotic Distractor 400 is inserted from the posterior aspect of the **spine** and comprises a barrel portion 410 terminating at its distal end 412 in a disc penetrating portion 420 which is shown interposed within the disc space between **two** adjacent vertebrae V. The disc **penetrating** portion 420 terminates distally into a leading bullet-shaped front end 422 which facilitates the...within the disc space and resistant to backing out as the compressive forces of the **spine** upon the disc penetrating portion 420 tend to urge it forward, while simultaneously the circumferential...

...Posterior Long Distractor 400 exceedingly stable.

Referring to Figure 20, in preparation for the bone **removal** step, the Posterior Long Lordotic Distractor 400 is shown with the disc penetrating portion 420 in place between the adjacent vertebrae V to restore and maintain lordosis of the **spine** . An Outer Sleeve 140 described above , in reference to Figure 5, is properly seated over...

...Distractor 400 using a mallet and the already described Driver Cap 160. While the bone **removal** step may be performed by either the drilling method described above in reference to Figures...

...the Posterior Long Lordotic Distractor 400 undisturbed until sufficient space has been created by the **removal** of bone at least as great as the thickness of the wall of the trephine 270 itself to allow for the unobstructed **removal** of the Posterior Long Lordotic Discractor 400.

If the ''Trephine Method" described above in reference...

...concentrically seated relative to the barrel portion 410, the Inner Sleeve 242 alone would be **removed** , and the trephine 270 would then be placed over the Posterior Long Lordotic Distractor 400...

...the saw-like sharp cutting teeth 271 of the trephine 270 shown in Figure 11B **removes** a pach of bone equal to the distance of the splaying cut of

each of...

...than the wall chickness of the trephine 270 itself. Thus, once the trephine 270 is **removed** , left behind is a semicylindrical space outlining each of the arcs of bone cut from...

...21 and 22, since the vertebrae V are placed into lordosis prior to the bone **removal** seep, the space S created by the bone **removal** is cut at an angle relative to the vertebrae V in the shape of a...

...which corresponds to the shape of the cylindrical implant I. In this manner, the cyclindrical **implant** I with parallel walls may be inserted between adjacent **vertebrae** V which have been stabilized for fusion in angular relationship to each other so as to preserve the normal curvature of the **spine** .

Referring to Figures 23 and 24, an elevational side view and a top plan view...

...dural sac and nerves while work is being performed on the contralateral side of the **spine** , If the Posterior Short Lordotic Distractor 500 were other than stable, injury to these structures...

...Referring to Figure 25, an Anterior Long Lordotic Distractor 600 for use anteriorly within the **spine** is shown. It can be seen chat the configuration of the disc penetrating portion 620...620. The Anterior Long Lordotic Distractor 600 serves to restore and maintain lordosis of the **spine** by distraction or the adjacent **vertebrae** V. As described above for the Posterior Short Lordotic distractor 500, it is appreciated that...

...within the disc space and further held there by the considerable ccnpressive loads within the **spine** .

Referring to Figure 28, because of the stability thus provided, a further derivative advantage is...

...with the vertebrae V and the extended portions 720 and 722 would ensure the proper **rotatory** alignment.

A further advantage, to be discussed in more detail subsequently, is chat the extended...

...a Posterior Lordotic extended Outer Sleeve 800 for use from the posterior approach of the **spine** is shown. The Posterior Lordotic Extended Outer Sleeve 800 comprises a hollow tubular member 802...

...the extended portions 820 and 822 are configured to restore and maintain lordosis of the **spine** similar to the disc penetrating portion 420 of the Posterior Long Lordotic Distractor 400, the...

...31, an Anterior Extended Outer Sleeve 900 for use from the anterior approach or the **spine** is shown. The Anterior Lordotic Extended Outer Sleeve 900 comprises a hollow tubular member 902...

...the extended portions 920 and 922 are configured to restore and maintain lordosis of the **spine** from the anterior approach similar to the disc penetrating portion 620 of the Anterior Long...for use anteriorly is shown in the singular form and in use in the lumbar **spine** , it is understood that it may take a double barrelled form and in either form, be used throughout the **spine** .

Referring to Figures 33 and 34, a Lumbar Dual Extended Outer Sleeve is shown and...

...hollow tubular members 1101 and 1102, in order to maintain the normal curvature of the **spine** by correcting the angular relationships of the vertebrae V. The extended portion 1121, is tapered...

...engaging the vertebrae V.
Each of the hollow tubular members 1101 and 11.02 are **displaced** from each other ideally the sum of the difference between the minor and major diameters of two threaded spinal **implants** I combined, but not less than that difference for one implant I, as it is...

...to have the threads of one implant nest interposed to the threads of the other **implant** I such that they **both** occupy a common area between them. Typically, the walls of each hollow tubular members 1101...

...hollow tubular members 1101 and 1102 may be placed closer together so that two spinal **implants** I may be placed closer together when inserted within the disc space between adjacent vertebrae W. The hollow tubular member 1101 and 1102 can be overlapped or **displaced** from each other so as to control the distance between implants when the Dual Extended Outer Sleeve is utilized and **two** **implants** implanted
The hollow tubular members 1101 and 1102 may be bridged in part or wholly...

...V, but limited in length so as not to over penetrate beyond the vertebrae once **inserted** .
Referring to Figure 35, a **second** Dual Extended Outer Sleeve 1200, is shown. The Dual Extended Outer Sleeve 1200 is similar...

...that the lordotic distractor for use posteriorly when referring to their use in the lumbar **spine** , would be used anteriorly if applied to the thoracic **spine** , either in the single or double-barrel form. This is because the Choracic **spine** is normally curved into kyphosis which is the reverse of lordosis. That is, in approaching the Choracic **spine** anteriorly, it would be desirable to distract the back of the disc space more than...

...Anterior Short Lordotic Distractors, though referred to previously as lordotic when placed into the lumbar **spine** from the posterior approach, would now more correctly, when placed in the thoracic **spine** from the anterior approach be called Kyphotic Thoracic
It can readily be appreciaced that the...

...41, shown is the apparatus 1350 for use in installing an improved interbody spinal fusion **implant** 1300 having one or more flat sides as disclosed in co-pending application filed on February 17, 1995, entitled IMPROVED INTERBODY SPINAL FUSION **IMPLANTS** which is incorporated herein by reference. The apparatus 1350 comprises a Dual Cuter Sleeve 1310...

...each having an internal diameter slightly larger than the outer diameter of the spinal fusion **implant** 1300. The cylindrical tubes 1352, 1354 are in communication with each other along their length and are **displaced** from each other ideally a distance that is slightly greater than the sum of the diameters of two spinal fusion **implants** 1300 placed side-by-side with the flat sides 1302 of each spinal fusion **implant** 1300 couching. The cylindrical tubes 1352 and 1354 are joined longitudinally such that they are...

...base of the adjacent vertebrae V.
Preferring specifically to Figure 36, the apparatus 1350 is **introduced** over **two** Long Distractors 1320 and 1322 placed side-by-side and

protruding anteriorly from the vertebrae...

...held via foot plate 1360 and the prongs 1364a-1364f. Thus, it is possible to **remove** either one, or if desired, both of the long distractors 1320 and 1322. The dual outer sleeve has been described above for **inserting two implants** each having at least one flat side, may have extended portions for intradiscal insertion which...

...Sleeve 1350 has been fully seated, one of the Long Distractors 1320 and 1322 is **removed** and the surgeon may drill the interspace D utilizing drill 250 using each of the...

...1354 to guide the drill 250 in order to create overlapping holes in which the **spinal** fusion **implants** 1300a and 1300b may be **inserted** . It is also appreciated by those skilled in the art, that a hollow inner sleeve...

...that the tubular members can be of a variety of shapes and sizes. Further, the **removal** of disc and bone may be accomplished by the use of a burr, or a...

...used to insert the spinal fusion implants 1300a and 1300b preferably by linear advancement. The **implant** driver instrument 350 may be used to either insert or to remove the spinal fusion implants 1300a and 1300b.

Once affixed to the **implant** Driver 350, the **spinal** fusion **implant** 1300a is then **introduced** through one of the hollow cylindrical tubes 1352, 1354 and driven into the interspace D by the application of an impaction force transmitted through the **implant** driver instrument 350. Once the spinal fusion **implant** 1300a is **inserted** into the interspace D, the surface roughenings of the outer surface of the spinal fusion implant 1300a engage the bone of the vertebrae V and the **implant** Driver 350 is detached from the spinal fusion implant 1300a. The **implant** driver instrument 350 is then **withdrawn** from the Dual Outer Sleeve 1350 and the spinal fusion **implant** 1300a is fully installed and inset in the interspace D as shown in Figure 41.

Once a first spinal fusion implant 1300a is inserted into the interspace D, a second **spinal** fusion **implant** 1300b is driven into the interspace D so that the flat side 1302a or 1302b of each spinal fusion **implant** 1300a and 1300b are adjacent to each other and are touching. In this manner, two spinal fusion **implants** 1300a and 1300b are implanted within the interspace D and engage the bone of the adjacent vertebrae V without exceeding the width of the **spinal** column. It is appreciated that there are other ways that two spinal **implants** can have complimentary shapes and that they can be inserted by linear **advancement** through a single (**both** at once; or dual outer sleeve having intradiscal extended members for stabilization, distraction, and/or...

...While the present invention has been described in association with the implant of a threaded **spinal** implant, it is recognized chat other forms of **implants** may be used with the present method. For example, dowels, made from bone or artificial materials, knurled or irregularly shaped cylinders or partial cylinders, or any other shaped **implants** that can be **introduced** through the outer sleeve may be used. Being able to perform the procedure through the...

...Further preferred embodiments of the invention are as follows:

According to a first aspect, a **spinal** distractor is provided for use in **spinal** fusion surgery for **positioning two** adjacent vertebrae in selected relationship to each other, said **spinal** distractor comprising a body, and a disc penetrating extension extending from said body for insertion...

...disc space between the two adjacent vertebrae and for bearing against adjacent endplates of the **two** adjacent vertebrae, said disc **penetrating** extension having a first portion for bearing against one of the adjacent endplates and a...

...body along at least a portion of their length.

According to a second aspect, a **spinal** distractor is provided for use in **spinal** fusion surgery for **positioning** **two** adjacent vertebrae in selected relationship to each other, said **spinal** distractor comprising: a body, and a disc penetrating extension from said body for insertion into...

...disc space between the two adjacent vertebrae and for bearing against adjacent endplates of the **two** adjacent vertebrae, said disc **penetrating** extension having a first portion for bearing against one of the adjacent endplate and a...

...portion for bearing against the other of the adjacent endplates, said first and second portions **diverging** away from said body along at least a portion of their length, said disc penetrating...

...said disc penetrating extension into the disc space.

According to a third aspect, in the **spinal** distractor according to the first aspect, said disc penetrating extension has a tapered front end ...

...said disc penetrating extension into the disc space.

Preferably, according to a fourth aspect, the **spinal** distractor according to one of the afore-mentioned aspects further comprises means for limiting the...

...penetrating extension into the disc space.

Further preferably, according to a fifth aspect, in the **spinal** distractor according to the fourth aspect, limiting means comprises a shoulder on said body at...

...preventing said body from entering the disc space.

According to a sixth aspect, in the **spinal** distractor according to one of the afore-mentioned aspects, said body is **removably** attached to said disc penetrating extension.

According to a seventh aspect, in the **spinal** distractor according to one of the fifth or sixth aspect, said disc penetrating extension includes...

...juncture of said disc penetrating extension and said body.

According to an eighth aspect, the **spinal** distractor according to one of the afore-mentioned aspects further comprises means for engaging the two adjacent vertebrae.

According to a ninth aspect, in the **spinal** distractor according to the eighth aspect, said engaging means includes a prong.

According to a tenth aspect, the **spinal** distractor according to the sixth aspect further comprises means for limiting the depth of insertion ...

...said disc penetrating extension into the disc space.

According to an eleventh aspect, in the **spinal** distractor according to the tenth aspect, said limiting means comprises a head associated with said...

...dimensioned to prevent entry into the disc space.

According to a twelfth aspect, in the **spinal** distractor according to the eleventh aspect, said head has a low profile so as to...

...protrusion of said head from the two adjacent vertebrae.

According to a thirteenth aspect, the **spinal** distractor according to the tenth aspect comprises an impacting surface at the juncture of said ...

...the exterior surface of the two adjacent vertebrae.

According to a fourteenth aspect, in the **spinal** distractor according to the sixth or the tenth aspect, said disc penetrating extension comprises means...

...said disc penetrating extension from the disc space.

According to a fifteenth aspect, in the **spinal** distractor according to one of the afore-mentioned aspects, said body is a barrel member.

According to a sixteenth aspect, in the **spinal** distractor according to one of the afore-mentioned aspects, said disc penetrating extension has surface irregularities.

According an seventeenth aspect, in the **spinal** distractor according to the sixteenth aspect, said surface irregularities include ratchetings.

According to an eighteenth aspect, in the **spinal** distractor according to the sixteenth aspect, said surface irregularities include knurling.

According to a nineteenth aspect, in the **spinal** distractor according to one of the afore-mentioned aspects, said body has means for engaging ...

...said disc penetrating extension from the disc space.

According to a twentieth aspect, in the **spinal** distractor according to the nineteenth aspect, said engaging means for engaging an extraction device includes...

...mating member for mating with an extraction device.

According to a twenty-first aspect, the **spinal** distractor according to one of the first and second aspects comprises an impacting surface proximate...

...exterior surface of the two adjacent vertebrae.

According to a twenty-second aspect, in the **spinal** distractor according to the second aspect, said first and second portions **diverge** away from said body along at least a portion of their length.

According to a twenty-third aspect, the **spinal** distractor according ...an opening for providing protected access to the disc space and the adjacent vertebrae, said **spinal** distractor passing through said opening.

According to a twenty-fourth aspect, in the **spinal** distractor according to the twenty-third aspect, said opening is sized to permit passage of said disc penetrating extension of said **spinal** distractor through said opening.

According to a twenty-fifth aspect, the **spinal** distractor according one of the twenty-third and twenty-fourth aspects further comprises bone **removal** means having a portion sized for passage through said opening for forming through said guard member an implantation space across the disc space.

According to a twenty-sixth aspect, the **spinal** distractor according to one of twenty-third to twenty-fifths aspects further comprises an implant...

34/3,K/2 (Item 2 from file: 348)
DIALOG(R)File 348:EUROPEAN PATENTS

01324336
A spinal distractor
Ruckgratausdehnungsvorrichtung
Ecarteur spinal
PATENT ASSIGNEE:
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PATENT (CC, No, Kind, Date): EP 1129668 A1 010905 (Basic)
APPLICATION (CC, No, Date): EP 2001114044 960226;
PRIORITY (CC, No, Date): US 396414 950227
DESIGNATED STATES: AT; BE; CH; DE; DK; ES; FR; GB; GR; IE; IT; LI; LU; MC; NL; PT; SE
RELATED PARENT NUMBER(S) - PN (AN):
EP 812167 (EP 96907088)
RELATED DIVISIONAL NUMBER(S) - PN (AN):
(EP 2003014398)
INTERNATIONAL PATENT CLASS: **A61B-017/17** ; A61F-002/46; A61F-002/44
ABSTRACT WORD COUNT: 152
NOTE:
Figure number on first page: 1

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SPEC A	(English)	200136	22306
Total word count - document A			23164
Total word count - document B			0
Total word count - documents A + B			23164

Ecarteur spinal
INTERNATIONAL PATENT CLASS: **A61B-017/17** ...

...SPECIFICATION wound area.
Further, if the disc tissue in the area to be reamed has been **removed** previously, as per the preferred method, then the patient's own bone of good quality...

...Once away from the surgical wound, this material may be used to load the spinal **implant** or placed deep within the interspace to participate in the fusion.
The method of actually producing the surgical hole within the **spine** is variable. As shown in Figure 11C, in an alternative embodiment Drill end 250 has...

...the method, the hole to be formed corresponds to the minor diameter of the spinal **implant** . Trephine 270, a hollow, tubular member with sharp cutting teeth 251 at its proximal end...

...the "Trephine Method" as the bony arcs are not so much being reamed out and **removed** as they are simply being cut into the bone where these arcs

of bone are...

...when the Trephining Method has been completed and the Trephine 270 and Inner Sleeve 242 **removed** , unlike in the preferred embodiment where the hole is drilled out, it remains necessary to **remove** both the two arcs of bone, and any interposed material. Nevertheless, this is very easily ...

...the perpendicularly cutting arm 278 of instrument 272 so that as handle portion 274 is **rotated** , the cutting arm 278 is also **rotated** , cutting the arcs of bone and liberating them from their last attachments. These portions of bone are then **rem**oved utilizing this instrument or a long forceps, and then placed within the implants or otherwise...

...Figures 12 and 13, while in the preferred embodiment of the present invention the spinal **implant** I, is essentially self-tapping, if the bone is unusually hard it may be desirable to form the thread pattern within the interspace prior to the **insertion** of the **implant** I. To that end, as shown in Figure 12, Tap 280 has a threadcutting portion...

...to a handle portion 292, which has been designed to give mechanical advantage to the **rotation** of the instrument for the purpose of cutting threads. The lower portion of handle 290...number 1 to 8, but preferably 4, function to accumulate the bony material which is **removed** during the thread cutting process. In that regard, in the ideal embodiment, the thread cutting...

...diameter is slightly less than the major diameter of the implant.
With Tap 280 now **removed** , and Sleeve 140 still in place, the surgical site is now fully prepared to receive the spinal implant I. In the preferred embodiment of the spinal implant, the **implant** has been enhanced by the use of, application to, and filling with fusion promoting, enhancing, and participating substances and factcrs. Thus, the **implant** may be fully prepared for **insert**ion as provided to the operating surgeon. However, at the present time, human bone is most...

...mechanism 312 is stable during the clockwise cutting procedure, and yet allows for the rapid **disconnection** of the two components once the cutting is completed.
Because of the high interference between...

...portion 304, and the relative weakness of the cancellous bone beingharvested, it is possible to **remove** the Trephine 300 while still drilling, and to have it extract the core of bone...

...core of bone would remain fixed at its base, then with the drive mechanism 308 **removed** , a corkscrew 408 shown in Figure 14C is introduced though the central opening of rear...

...portion 306 and it can no longer advance. As corkscrew 408 is continued to be **turned** further, it will cause the core of bone to be pulled rearward, as in **removing** a cork from a wine bottle. Trephine 300 has a barrel portion 304 continuous with...

...portion 302 having an inner diameter just less than the inner diameter of the spinal **implant** I to be loaded.
Referring to Figure 14B, the Trephine 300 with its core of...

...flange 344. The plunger shaft 326 of instrument 320 is then prepared for attachment by **rotating** knob 332 counterclockwise such that the plunger

372 is pulled via the long threaded shaft...

...collar 330 are then advanced longitudinally into diametrically opposed paired L slots 340 and then **rotated** clockwise to complete this assembly. At the other end of instrument 320, a spinal **implant** I is engaged through its female rectangular slot 364 by a rectangular protruding bar extending...

...female aperture centered within the female slot 364 of the spinal implant. With the spinal **implant** I secured to end plug 324 and the opposite end of the implant I presenting 332 is then **rotated** clockwise, the plunger 372 proximal the threaded shaft 328 is then forcibly, but controllably driven forward down the barrel 304 ejecting the bone graft directly into the spinal **implant** I. As the bone graft is greater in length than the interior of the spinal **implant** , with further compression the bone is forced into the radially disposed apertures through the wall...

...the device communicating from the central cavity to the exterior.

End plug 324 is then **removed** from apparatus 320. Using end plug 324 as a handle, end cap 374 shown in Figure 16 is secured to the open end of the spinal **implant** I. The **implant** is then disassociated from end plug 324 by **rotating** knob 334 counterclockwise.

Referring to Figure 16, an Implant Driver instrument which may be used to either **insert** or to **rem**ove said **implant** I is shown. Driver 350 has at its far end 362, a rectangular protrusion 398...

...hand barrel 360 to knob 354 where it can be rotationally controlled. Threaded portion 353 **screws** into a female aperture central slot 364, urging 353 into 364, and binding them together such that instrument 350 can be **rotated** via paired and diametrically opposed extending arms 366 and in either direction while maintaining contact with the implant.

Referring to Figure 17, affixed to the Driver 350, the **implant** I is then **introduced** through the Outer Sleeve 140 and **screwed** into the interspace opposed between the two prepared **vertebrae** V until such time as the leading edge of the **Implant** Cap 374 reaches the depth of the prepared hole at which time its forward motion...

...drilled out. This allows for a progressive feel to the surgeon as the implant is **screwed** home.

As described previously, with the use of the Tap 280, this terminal resistance to...

...to the surgeon. Again, as with the Tap 280, visual monitoring of the depth of **insertion** of the **implant** is provided to the surgeon by observing the progressive approximation of the forward surface 370...

...abut surface 172 of the Outer Sleeve 140, prohibiting any further installation of the spinal **implant** .

Referring to Figure 18, once the **implant** has been fully installed, the Driver 350 is dissociated from the implant I by **turning** knob 354 in a counterclockwise direction. The Driver 350 is then **withdrawn** from the Outer Sleeve 140, then the Outer Sleeve 140 is **removed** . This leaves the **implant** fully installed and inset to the determined depth as shown in Figure 18.

Attention is then redirected to the other, or first, side of the **spine** . A dural nerve root retractor is used to retract the neural structures medially, bringing into...

...of the Short Distractor 120, lying flush on the canal floor. Utilizing

apparatus 152, extended **screw** portion 116 is inserted into the female threaded portion 114 of the Short Distractor 120...

...152 is engaged to the female rectangular portion 118 of the Short Distractor 120. Then **turning** rearward facing portions 108 and 110, utilizing the knob 136 of Figure 2, the Long...

...the implantation of the spinal implant as already placed, is then repeated such that both **spinal** **implants** come to lie side by side within the interspace. Though not necessary, circlage or other...

...Predistraction And Utilizing A Guarded Sleeve System Is Disclosed
Because of the absence of the **spinal** cord and nerve roots, it is generally possible to visualize in one instance the entire width of the disc space from side to side throughout the cervical, thoracic, or lumbar **spine** . In the preferred embodiment of the anterior interbody fusion, **implants** are placed side by side from anterior to posterior parallel to the interspace and extending...

...the transverse width of the disc space is insufficient to allow for the use of **two** **implants** , each of which would be large enough to protrude to the required depth into the adjacent **vertebrae** , then a singular and significantly larger **implant** may be placed centrally. With this in mind, and in light of the very detailed...

...in regard to the method of posterior lumbar interbody fusion, a brief discussion of anterior **spinal** interbody fusion with dual **implant** installation will suffice, and the method for installation of a large, singular midline graft will become obvious.
The interspace to be fused is exposed anteriorly. The soft tissues are **withdrawn** and protected to either side, and if necessary, above and below as well. It is...

...great bulk of the nuclear disc portion. (Alternatively, the disc can be left to be **removed** via the drill later.) The surgeon then notes and marks a point midway from side to side anteriorly. He then **inserts** Long Distractor 100 centering it on a point midway between the point just noted and...

...inserted, then its exact duplicate is inserted anteriorly equidistant to the other side of the **spine** . As the barrel portion 106 of Long Distractor 100 is exactly of the same major diameter as the spinal **implant** I looking coaxially on end, the surgeon can then asses the anticipated side by side...

...implanted.
Referring to Figures 7C and 7D, a Dual Outer Sleeve 340 consisting of a **pair** of hollow tubes is then **introduced** over the side by side Long Distractors 100 protruding anteriorly from the **spine** . The Dual Outer Sleeve 340 is comprised of two hollow tubular members identical in size **displaced** from each other ideally the sum of the difference between the minor and major diameters of **both** **implants** combined, but not less than that difference for one implant, as it is possible to...

...slightly greater than two times the difference between the major and minor diameters of the **implant** (the sum of **both**) the distance may be considerably greater. Whereas in the preferred embodiment the paired tubular portions...
...may be inclined or declined relative to each other such that they either converge or **diverge** at their proximal ends. The paired tubular portions

348, may be bridged in part or...

...rigidly held via Foot Plate 344 and the prongs 342. Thus, it is possible to **remove** either one, or if desired, both of the Long Distractor rods utilizing Long Distractor puller...

...is then the surgeon's choice to work on one or both sides of the **spine** . As per previous discussion, the surgeon may drill the interspace utilizing the Inner Sleeve 242...

...the Long Distractors in place as per the "Trephine Method".
Tapping, if necessary, and the **insertion** of the **implants** then occurs through the protective Outer Sleeve 340. Once the **implants** have been fully **inserted** , the Outer Sleeve is **removed** .
Having utilized the Drill method, or "Trephine Method", with or without an Inner Sleeve to...

...the interspace, or preferring the ability to directly visualize the cap being used, or the **implant** being **inserted** , may choose to **remove** the Outer Sleeve after the insertion of the first prosthesis to maintain stability, or prior...

...Preferred Embodiment For Method Of Anterior Interbody Fusion
As previously described for the posterior lumbar **spine** , alternatively, one can employ the "Trephine Method" as has been described in detail.
As a...

...the preferred embodiment, it is nevertheless within the scope of this invention that one could **remove** the Outer Sleeve as there are no neural structures requiring protection, and **insert** the **implants** directly rather than through the Outer Sleeve.
As yet a further alternative of this method...

...depth into the opposed vertebral bodies is such that it is not possible to place **two** such **implants** side by side, then only a single implant which may be of significantly increased diameter...

...or the "Trephine Method".
Referring to Figures 16-18, a cylindrical embodiment of the spinal **implant** I of the present invention is shown. In Figure 16 the implant I is shown...
...I is shown installed in the disc space D, between the adjacent vertebrae.
The cylindrical **implant** I comprises a hollow tubular member which in the preferred embodiment is made of an...

...in detail below.

Detailed Description of Alternative Embodiments of Apparatus and Method
When the human **spine** is viewed from the side, it consists of a balanced series of curves, as opposed...

...line when viewed from the side. In both the cervical and lumbar regions of the **spine** , the **vertebrae** relate to each other so as to form curves where the apex of said curves is **displaced** forward within the body, and those segments of the **spine** are said to be in lordosis. In contradistinction, in the thoracic portion of the **spine** , the **vertebrae** relate to each other so as to form a curve where the apex of said curve is **displaced** posteriorly and is said to be in kyphosis. The methods and

instrumentation of the present...

...vertebrae in the correct anatomic lordosis or kyphosis. Where it is possible to approach the **spine** from various angles each of the devices, then has different forms appropriate to that specific...

...of restoring and maintaining lordosis of adjacent vertebrae V from the posterior approach of the **spine** is shown. The Posterior Long Lordotic Distractor 400 is inserted from the posterior aspect of the **spine** and comprises a barrel portion 410 terminating at its distal end 412 in a disc penetrating portion 420 which is shown interposed within the disc space between **two** adjacent vertebrae V. The disc **penetrating** portion 420 terminates distally into a leading bullet-shaped front end 422 which facilitates the...within the disc space and resistant to backing out as the compressive forces of the **spine** upon the disc penetrating portion 420 tend to urge it forward, while simultaneously the circumferential...

...Posterior Long Distractor 400 exceedingly stable.
Referring to Figure 20, in preparation for the bone **removal** step, the Posterior Long Lordotic Distractor 400 is shown with the disc penetrating portion 420...

...Distractor 400 using a mallet and the already described Driver Cap 160. While the bone **removal** step may be performed by either the drilling method described above in reference to Figures...
...the Posterior Long Lordotic Distractor 400 undisturbed until sufficient space has been created by the **removal** of bone at least as great as the thickness of the wall of the trephine 270 itself to allow for the unobstructed **removal** of the Posterior Long Lordotic Distractor 400..
If the "Trephine Method" described above in reference...

...concentrically seated relative to the barrel portion 410, the Inner Sleeve 242 alone would be **removed** , and the trephine 270 would then be placed over the Posterior Long Lordotic Distractor 400...

...the saw-like sharp cutting teeth 271 of the trephine 270 shown in Figure 11B **removes** a path of bone equal to the distance of the splaying out of each of...

...than the wall thickness of the trephine 270 itself. Thus, once the trephine 270 is **removed** , left behind is a semi-cylindrical space outlining each of the arcs of bone cut...

...21 and 22, since the vertebrae V are placed into lordosis prior to the bone **removal** step, the space S created by the bone **removal** is cut at an angle relative to the vertebrae V in the shape of a...
...which corresponds to the shape of the cylindrical implant I. In this manner, the cylindrical **implant** I with parallel walls may be inserted between adjacent **vertebrae** V which have been stabilized for fusion in angular relationship to each other so as to preserve the normal curvature of the **spine** .
Referring to Figures 23 and 24, an elevational side view and a top plan view...

...dural sac and nerves while work is being performed on the contralateral side of the **spine** . If the Posterior Short Lordotic Distractor 500 were other than stable, injury to these structures...

...Referring to Figure 25, an Anterior Long Lordotic Distractor 600 for use anteriorly within the **spine** is shown. It can be seen that the

configuration of the disc penetrating portion 620...620. The Anterior Long Lordotic Distractor 600 serves to restore and maintain lordosis of the **spine** by distraction of the adjacent **vertebrae** V. As described above for the Posterior Short Lordotic distractor 500, it is appreciated that...

...within the disc space and further held there by the considerable compressive loads within the **spine** .

Referring to Figure 28, because of the stability thus provided, a further derivative advantage is...

...with the vertebrae V and the extended portions 720 and 722 would ensure the proper **rotatory** alignment.

A further advantage, to be discussed in more detail subsequently, is that the extended...

...a Posterior Lordotic Extended Outer Sleeve 800 for use from the posterior approach of the **spine** is shown. The Posterior Lordotic Extended Outer Sleeve 800 comprises a hollow tubular member 802...

...the extended portions 820 and 822 are configured to restore and maintain lordosis of the **spine** similar to the disc penetrating portion 420 of the Posterior Long Lordotic Distractor 400, the...

...31, an Anterior Extended Outer Sleeve 900 for use from the anterior approach of the **spine** is shown. The Anterior Lordotic Extended Outer Sleeve 900 comprises a hollow tubular member 902...

...the extended portions 920 and 922 are configured to restore and maintain lordosis of the **spine** from the anterior approach similar to the disc penetrating portion 620 of the Anterior Long...for use anteriorly is shown in the singular form and in use in the lumbar **spine** , it is understood that it may take a double barrelled form and in either form, be used throughout the **spine** .

Referring to Figures 33 and 34, a lumbar Dual Extended Outer Sleeve is shown and...

...hollow tubular members 1101 and 1102, in order to maintain the normal curvature of the **spine** by correcting the angular relationships of the vertebrae V. The extended portion 1121, is tapered...

...for engaging the vertebrae V.

Each of the hollow tubular members 1101 and 1102 are **displaced** from each other ideally the sum of the difference between the minor and major diameters of two threaded spinal **implants** I combined, but not less than that difference for one implant I, as it is...

...have the threads of one implant I nest interposed to the threads of the other **implant** I such that they **both** occupy a common area between them. Typically, the walls of each hollow tubular members 1101...

...hollow tubular members 1101 and 1102 may be placed closer together so that two spinal **implants** I may be placed closer together when inserted within the disc space between adjacent vertebrae W. The hollow tubular member 1101 and 1102 can be overlapped or **displaced** from each other so as to control the distance between implants when the Dual Extended Outer Sleeve is utilized and **two** **implants** implanted

The hollow tubular members 1101 and 1102 may be bridged in part or wholly...

...V, but limited in length so as not to over penetrate beyond the vertebrae once **inserted** .

Referring to Figure 35, a **second** Dual Extended Outer Sleeve 1200, is shown. The Dual Extended Outer Sleeve 1200 is similar...

...that the lordotic distractor for use posteriorly when referring to their use in the lumbar **spine** , would be used anteriorly if applied to the thoracic **spine** , either in the single or double-barrel form. This is because the thoracic **spine** is normally curved into kyphosiswhich is the reverse of lordosis. That is, in approaching the thoracic **spine** anteriorly, it would be desirable to distract the back of the disc space more than...

...Anterior Short Lordotic Distractors, though referred to previously as lordotic when placed into the lumbar **spine** from the posterior approach, would now more correctly, when placed in the thoracic **spine** from the anterior approach be called Kyphotic Thoracic Distractors.

It can readily be appreciated that...

...41, shown is the apparatus 1350 for use in installing an improved interbody spinal fusion **implant** 1300 having one or more flat sides as disclosed in co-pending application filed on February 17, 1995, entitled IMPROVED INTERBODY SPINAL FUSION **IMPLANTS** which is incorporated herein by reference. The apparatus 1350 comprises a Dual Outer Sleeve 1310...

...each having an internal diameter slightly larger than the outer diameter of the spinal fusion **implant** 1300. The cylindrical tubes 1352, 1354 are in communication with each other along their length and are **displaced** from each other ideally a distance that is slightly greater than the sum of the diameters of two spinal fusion **implants** 1300 placed side-by-side with the flat sides 1302 of each spinal fusion **implant** 1300 touching. The cylindrical tubes 1352 and 1354 are joined longitudinally such that they are...

...base of the adjacent vertebrae V.

Referring specifically to Figure 36, the apparatus 1350 is **introduced** over **two** Long Distractors 1320 and 1322 placed side-by-side and protruding anteriorly from the vertebrae...

...held via foot plate 1360 and the prongs 1364a-1364f. Thus, it is possible to **remove** either one, or if desired, both of the long distractors 1320 and 1322. The dual outer sleeve has been described above for **inserting** **two** **implants** each having at least one flat side, may have extended portions for intradiscal insertion which...

...Sleeve 1350 has been fully seated, one of the Long Distractors 1320 and 1322 is **removed** and the surgeon may drill the interspace D utilizing drill 250 using each of the...

...1354 to guide the drill 250 in order to create overlapping holes in which the **spinal** fusion **implants** 1300a and 1300b may be **inserted** . It is also appreciated by those skilled in the art, that a hollow inner sleeve...

...that the tubular members can be of a variety of shapes and sizes. Further, the **removal** of disc and bone may be accomplished by the use of a burr, or a...

...used to insert the spinal fusion implants 1300a and 1300b preferably by linear advancement. The **implant** driver instrument 350 may be used to either insert or to remove the spinal fusion implants 1300a and 1300b.

Once affixed to the **implant** Driver 350, the **spinal** fusion **implant** 1300a is then **introduced** through one of the hollow cylindrical tubes 1352,1354 and driven into the interspace D by the application of an impaction force transmitted through the **implant** driver instrument 350. Once the spinal fusion **implant** 1300a is **inserted** into the interspace D, the surface roughenings of the outer surface of the spinal fusion implant 1300a engage the bone of the vertebrae V and the **implant** Driver 350 is detached from the spinal fusion implant 1300a. The **implant** driver instrument 350 is then **withdrawn** from the Dual Outer Sleeve 1350 and the spinal fusion **implant** 1300a is fully installed and inset in the interspace D as shown in Figure 41.

Once a first spinal fusion implant 1300a is inserted into the interspace D, a second **spinal** fusion **implant** 1300b is driven into the interspace D so that the flat side 1302a or 1302b of each spinal fusion **implant** 1300a and 1300b are adjacent to each other and are touching. In this manner, two spinal fusion **implants** 1300a and 1300b are implanted within the interspace D and engage the bone of the adjacent vertebrae V without exceeding the width of the **spinal** column. It is appreciated that there are other ways that two spinal **implants** can have complimentary shapes and that they can be inserted by linear **advancement** through a single (**both** at once) or dual outer sleeve having intradiscal ...While the present invention has been described in association with the implant of a threaded **spinal** implant, it is recognized that other forms of **implants** may be used with the present method. For example, dowels, made from bone or artificial materials, knurled or irregularly shaped cylinders or partial cylinders, or any other shaped **implants** that can be **introduced** through the outer sleeve may be used. Being able to perform the procedure through the...

34/3,K/9 (Item 9 from file: 348)
DIALOG(R)File 348:EUROPEAN PATENTS

00828498
TRANSLATERAL SPINAL IMPLANT
TRANSLATERALE WIRBELSAULENIMPLANTATIE
ARTHRODESE TRANSLATERAL DU RACHIS
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Available Text	Language	Update	Word Count
CLAIMS B	(English)	200316	752
CLAIMS B	(German)	200316	644
CLAIMS B	(French)	200316	729
SPEC B	(English)	200316	5555
Total word count - document A			0
Total word count - document B			7680
Total word count - documents A + B			7680

...SPECIFICATION from the spinal fusion implant 200. Referring to Figure 9, an alternative embodiment of the **spinal** fusion **implant** of the present invention generally referred to by the numeral 300 is shown. The **spinal** fusion **implant** 300 has a substantially cylindrical .configuration having surface roughenings for stabilizing the implant 300 within the **intervertebral** space D. The surface roughenings comprise a surface knurling 320 such as, but not limited to, the diamond-shaped bone engaging pattern shown in Figure 9. The **spinal** fusion **implant** 300 may have surface knurling 320 throughout the entire external surface of the **spinal** fusion **implant** 300, throughout only a portion of the external surface, or any combination thereof, without departing...

...those circumstances where there is no undrilled bone in the disc space forward of the **spinal** fusion **implant** 300 to resist further forward advancement of the **implant** , surface knurling 320 is preferred as it produces an exceedingly high interference fit with the...

...the tendency to urge itself forward.
Referring to Figure 10, an alternative embodiment of the **spinal** fusion **implant** of the present invention is shown and is generally referred to by the numeral 400. The spinal fusion implant 400 has a

similar configuration to that of the **spinal** fusion **implant** 200, except that it comprises a partially cylindrical member having arcuate portions 402 and 404...

...wall that are flattened so as to present a first flat side 406. Alternatively, the **implant** 400 may have a **second** flat side that is diametrically opposite to the first flat side 406. The spinal fusion implant 400 is substantially the same as the **spinal** fusion **implant** 200, except that the openings 428 are positioned on the ratcheting 420 such that the...

...by the bone engaging edges 422.

Referring to Figure 11, an alternative embodiment of the **spinal** fusion **implant** of the present invention is shown and generally referred to by the numeral 500. The spinal fusion implant 500 is substantially identical to the **spinal** fusion **implant** 400 described above except that in place of ratchetings 420, it has surface knurling 520. The surface knurling 520 assists in the retaining of the **spinal** fusion **implant** 500 once it is **inserted** across the disc space between **two** adjacent **vertebrae** . It is recognized that the surface knurling 520 of the **implant** 500 may be combined with any of a number of other surface roughenings such as, but not limited to, ratchetings to assist in retaining the **spinal** fusion **implant** 500 across the disc space.

Referring to Figure 12, an alternative embodiment of the **spinal** fusion **implant** of the present invention generally referred to by the numeral 600 is shown. The spinal fusion implant 600 has the same structure as the **spinal** fusion **implant** 300 described above but instead of knurling 320 has a different surface roughening. The **spinal** fusion **implant** 600 has a surface roughening comprising of a blasted external surface 601 which may be...

...to provide an engagement surface for the vertebrae when inserted across the disc space. The **spinal** fusion **implant** has a **plurality** of openings 628, a **removable** cap 630 for accessing an internal chamber.

Referring to Figure 13, an alternative embodiment of the **spinal** fusion **implant** of the present invention generally referred to by the numeral 700 is shown. The **spinal** fusion implant 700 is similar to spinal fusion **implant** 400 described above except that it has openings in the form of horizontal slots 728...

...and vertical slots 729 on the cylindrical portion of the spinal fusion implant 700. The **spinal** fusion **implant** 700 has ratchetings 720 for engaging the bone of the **vertebrae** similar to the ratchetings 220 described above.

It is appreciated that the **spinal** fusion **implants** of the present invention may include any and all surface roughening configurations that either increase the surface area or interference fit of the **implant** and the **vertebrae** . It is appreciated that the ratchetings described above for the various embodiments of the **spinal** fusion **implants** of the present invention may also comprise a knurled or other surface roughenings in combination with the ratchetings to further enhance the retention of the **spinal** fusion **implant** across the disc space once **inserted** .

Referring to Figure 14, an alternative embodiment of the **spinal** fusion **implant** of the present invention is shown and generally referred to by the numeral 800. The spinal fusion implant 800 is similar in configuration to the **spinal** fusion implant 100 discussed above. However, instead of an external thread, the **spinal** fusion **implant** 800 has a **plurality** of longitudinal splines 810 along its external surface. The splines 810 are parallel to the central longitudinal axis L of the

implant 800 in the direction of insertion of the **implant** 800. The splines 810 have a sharp edge 812 and a sharpened leading end 814 to facilitate insertion of the **spinal** fusion **implant** 800 into the adjacent **vertebrae** . Located between the splines 812 are a plurality of slots 820 that allow bone growth...

...the internal chamber of the implant 800 during spinal fusion.

Referring to Figure 15, the **spinal** fusion implant 800 is shown inserted from the lateral aspect of the **spine** into a bore created across the disc space D and into the adjacent vertebrae V1)) and V2)) along the transverse width of the vertebrae V1)) and V2)). The **spinal** fusion **implant** 800 ...each of the adjacent vertebrae V1)) and V2)). The splines 810 function to engage the **vertebrae** V1)) and V2)) and stabilize the spinal fusion **implant** 800 once implanted. The splines 810 are oriented longitudinally with respect to the spinal fusion **implant** 800 to prevent any dislodgement of the **spinal** fusion **implant** 800 from between the **vertebrae** V1)) and V2)) as result of anterior to posterior motion of the **spine** . It is appreciated that the number of splines 810 and the configuration of the splines 810 can vary depending on the size of the **spinal** fusion **implant** 800 being implanted.

Referring to Figure 16, an alternative embodiment of the **spinal** fusion **implant** of the present invention is shown and generally referred to by the numeral 900. The **spinal** fusion **implant** 900 differs from the **implants** described above in that it is inserted in the disc space D between the adjacent vertebrae of the **spine** and not into a cylindrical bore created across the disc space. Therefore, the spinal fusion **implant** 900 does not require the **removal** of any portion of bone from the adjacent **vertebrae** as the spinal fusion **implant** 900 fits within the natural disc space between the adjacent **vertebrae** . However, the **removal** of at least a portion of the disc material present between the adjacent vertebrae is required for proper insertion.

The **spinal** fusion **implant** 900 comprises a rectangular **block** 901 having a top surface 902 and a bottom surface 904 for engaging the adjacent...

...described herein for engaging the bone of the adjacent vertebrae to promote firm stability. The **spinal** fusion **implant** 900 may be solid or hollow at least in part and have a plurality of...

...closed bottom wells for holding fusion promoting materials.

Referring to Figure 17, the spinal fusion **implant** 900 is shown implanted from the lateral aspect of the **spine** in the disc space D between two adjacent vertebrae V, V1)) and V2)) along the transverse width of the adjacent vertebrae V1)) and V2)). The **spinal** fusion **implant** 900 has a height that is substantially equal to the height of the disc space...

...and a width that approximates the depth of the vertebrae.

In the preferred embodiment, the **spinal** fusion **implant** 900 has a height in the range of 8 mm to 16 mm, with the...

...42 mm being the preferred length.

Referring to Figure 18, an alternative embodiment of the **spinal** fusion **implant** of the present invention is shown and generally referred to by the numeral 1000. The **spinal** fusion implant 1000 is similar to the spinal fusion **implant** 900, but has a narrower width such that more than one **spinal** fusion **implant** 1000 may be combined in a modular fashion for insertion within the disc space D between the adjacent vertebrae.

Referring to Figure 19, a plurality of spinal fusion **implants** 1000 are shown combined in a modular fashion inserted in the disc space D from the lateral aspect of the **spine** and along the transverse width of the vertebrae V1)) and V2)).

Referring to Figure 20, an alternative embodiment of the **spinal** fusion **implant** of the present invention is shown and generally referred to by the numeral 1100. The spinal fusion implant 1100 is inserted into the disc space between **two** adjacent **vertebrae** from the lateral aspect of the **spine** and along the transverse width of the **vertebrae** . The **implant** 1100 is dimensioned to replace the natural disc material present between two adjacent **vertebrae** . The **implant** 1100 has a generally rectangular body with curved sides 1102 and 1104. The top and...

...splines 1110 similar in structure and function as the splines 810 described above. As the **implant** 1100 is **inserted** in the disc space, the splines 1110 engage the bone of the adjacent **vertebrae** .

The **implant** 1100 is shown as being hollow with openings 1112 and slots 1114 in the outer...

...or wells in place of opening 1112 to permit bone ingrowth and incorporation of the **implant** 1100 into the **spinal** fusion mass. The interior of the **implant** 1000 may be accessed through the aperture 1120 which may be closed with a snap...

34/3,K/12 (Item 12 from file: 348)
DIALOG(R)File 348:EUROPEAN PATENTS

01267549
Guard having first and second passages for disc space surgery
Schutzvorrichtung mit zwei Durchfuhrungen zur Chirurgie des Zwischenwirbelraums
Dispositif protecteur avec deux passages pour chirurgie de l'espace intervertebrale
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INTERNATIONAL PATENT CLASS: **A61B-017/17**

...SPECIFICATION performing bilateral paired semihemilaminotomies and resecting the inner aspects of the facet joints adjacent the **spinal** canal while preserving the supra and interspinous ligaments.
Step 3. Beginning on the first side...
...vertebral bodies apart is being equally resisted by the powerful soft tissue structures about the **spinal** segment including the outer casing of the disc (the annulus fibrosus), various ligaments, capsular structures...

...from the neural structures. To insure that the Short Distractor remains in place until its **removal** is desired, various embodiments of the Short Distractor are available with varying degrees of resistance...

...preferred embodiment of the procedure, attention is then directed to the contralateral side of the **spine** .
Step 4. On the contralateral side of the same interspace the Long Distractor having at...

...Short Distractor would be placed on the second side. Then the Short Distractor would be **removed** from the first side and replaced with a larger Long Distractor so as to bring...

...In an alternative embodiment, the entire procedure is performed on the one side of the **spine** utilizing only the Long Distractor prior to repeating the procedure on the contralateral side of the **spine** . While this method can be performed in accordance with the remaining ...later.

Step 5. With the Short Distractor in place on the first side of the **spine** , and the matching Long Distractor in place on the second side of the **spine** , and with the dural sac and traversing nerve root safely retracted, the Outer Sleeve is...

...its optimal depth using the Impaction Cap and a mallet. The Long Distractor is then **removed** .

Step 6. An Inner Sleeve is then placed within the Outer Sleeve, and the interspace...

...Drill, Endmill, Reamer, or Trephine to drill, ream, or cut out the bone to be **removed** to either side, as well as any remaining interposed discal material. In the preferred method, utilizing a specially designed Endmill-Drill, it and the Inner Sleeve are **removed** as a unit, safely carrying away the bone and disc debris trapped within them from the **spinal** canal.

Step 7. If required, a thread forming Tap with penetration limiting means to control the depth of insertion, is then inserted through the Outer Sleeve.

Step 8. The prepared **implant** is then **inserted** utilizing the specialized Driver unit. It should be noted that the implant may be coated...

...than the inside diameter of the spinal implant to be loaded, but longer than the **spinal implant** . Utilizing an instrument designed for that purpose, the core of bone is then injected from...

...Driver Extractor instrument, the prepared implant is threaded into the prepared interspace. The instrumentation is **removed** from that side of the **spine** and attention is then redirected to the first side of the **spine** . A small retractor is utilized to move the dural sac and traversing nerve root medially...

...to protect them and allowing the direct visualization of the retained Short Distractor unit. Without **removing** the Short Distractor, it is reassembled to its shaft portion, essentially reconstituting itself into a Long Distractor. With the **inserted implant** now acting as the distractor on the opposite side, the Long Distractor is utilized to...

...while a Long Distractor having an outside diameter to the barrel portion corresponding to the **implant** to be **inserted** , that is 18mm, and having a diameter at the working end of perhaps 8mm, would...

...the ideal distraction, the Convertible Distractor would then be disassembled, the barrel and head portion **removed** , and the Short Distractor portion left deeply embedded and with its flanged head flat against...

...and driven flush to the bone if necessary, such impaction imploding any osteophytes not already **removed** , and assuring that the shoulder portion of the barrel comes to lie flat against the preferred embodiment, the Long Distractor is then **removed** and the Inner Sleeve is inserted into

the Outer Sleeve. Since the purpose of the...

...of the implant over the size of the drill, thus making it possible for the **insertion** of the **implant** to occur through the Outer Sleeve, the Inner Sleeve therefore measures 18mm in its outside...

...is 16,5mn in diameter.

Following the drilling procedure, the Drill and Inner Sleeve are **removed** as a single unit with the trapped interposed cartilaginous and bony debris. The depth of...

...inserted at this time and be appropriate to the minor and major diameters of the **implant** to be **inserted** and as with the Drill, controlled for its depth of penetration. The **spinal implant** would then be prepared for implantation by utilizing a Trephine to harvest a core of...

...this core of bone would be forcefully injected into the internal chamber of the spinal **implant** which would then be capped. Cap end forward, the fully loaded implant would then be attached to the Insertion Driver, down the Outer Sleeve and **screwed** into place with the depth of penetration limited by the Insertion instrument. The Insertion Driver is then unscrewed from the implant and **removed** from the Outer Sleeve. With the dural sac and nerve root retracted and protected, the Outer Sleeve would then be **removed** . This would complete the fusion procedure on that side, and then as described, the procedure...

...on the opposite side, and while nevertheless maintaining distraction at the site of the bone **removal** .

The following is a description of the "Trephine Method".

Having completed the exposure of the...

...only in that the barrel portion is of a precisely lesser diameter than the spinal **implant** . As in the preferred embodiment, the Outer Sleeve has an inner diameter only slightly greater than the **implant** to be **inserted** . Therefore, at this time, a first Inner Sleeve is inserted into the Outer Sleeve to...

...Sleeve is optimally seated using the Impaction Cap. The Cap and first Inner Sleeve are **removed** , but the Long Distractor and Outer Sleeve are left in place.

With the Long Distractor...

...methods, the Trephine, the Long Distractor, and the second Inner Sleeve, if utilized, are all **removed** . Since the Trephine cuts two arcs of bone but does not ream them out, a...

...portion at its working end is then inserted parallel to the disc space and then **rotated** through an arc of motion cutting the bases of the two longitudinally cut arcs, thus freeing them for **removal** through the Outer Sleeve. The space may then be tapped if required, and the implant is inserted as per the preferred **method** . As already mentioned, the "Trephine Method" can be used with or without the use of the Short Distractor on the contralateral side.

Applications of Method in Other Areas of the **Spine**

The following method is the preferred embodiment for performing anterior interbody fusion in the thoracic and lumbar **spines** . It is also appropriate in the cervical **spine** when the width of the **spine**

anteriorly is sufficient so that it is possible to place **two implants** side by side and such that each intrudes at least several millimeters into the substance of the opposed **vertebrae** and for the length of the **implants** .

The interspace to be fused is adequately exposed and the soft tissues and vital structures...

...possible by the absence of the neurological structures in relation to this aspect of the **spine** . The center line of the anterior aspect of the interspace is noted and marked. The disc is **removed** using first a knife and then curettes and rongeurs as needed. Alternatively, the disc may be left intact to be **removed** during the drilling stage of the procedure. However, as per the preferred embodiment of the procedure, having **removed** the great mass of the nucleus and the greater portion of the annulus anteriorly, Long...

...between the central marking line and the lateral extent of the anterior aspect of the **spine** as visualized.

The Dual Outer Sleeve with its common Foot Plate and Retention Prongs is...

...placed. The Dual Outer Sleeve is then seated firmly against the anterior aspect of the **spine** . Any spurs which would interfere with the flush seating of the Foot Plate to the anterior aspect of the **spine** should be **removed** prior to inserting the Long Distractors. Once the Outer Sleeve has been optimally seated, one of the Long Distractors is **removed** and in its place is inserted an Inner Sleeve and drill bit. The drill bit has as its outside diameter the minor diameter of the **implant** to be **inserted** . The Inner Sleeve is essentially equal in thickness to the difference between the minor and major diameters of the threaded **implant** .

A Stopped Drill is then utilized to prepare the opposed vertebral surfaces and to **remove** any remaining disc material interposed. If required, a Stopped Tap may be inserted through the Outer Sleeve and into the interspace to create a thread form. The properly prepared **implant** is then affixed to the **Insertion** Driver and passed through the Outer Sleeve down into the interspace and inserted until its depth of penetration is limited by the stop on the **Insertion** Driver. With the **implant** itself now in a **position** to act as a distractor, the Long Distractor is then **removed** from the contralateral side and the procedure repeated. When **both implants** are firmly in place, the outer sleeve may then be **removed** . The amount of countersinking of the implants may then be adjusted under direct vision.

Detailed...

...of the adjacent vertebrae. In the preferred embodiment the supraspinous ligament, the interspinous ligament, the **spinous** process, portions of the lamina, and most of the facet joints are preserved. However, while less desirable, these structures may be **removed** .

In the preferred method, a bilateral partial nuclear discectomy is then performed through bilateral openings...

...adjacent vertebral bodies and the interposed disc posteriorly.

Referring now to Figure 1, preferably after **removing** some portion of nuclear disc material, a Long Distractor 100 is inserted under direct vision...

...bone of the posterior vertebral bodies adjacent the posterior disc which have not already been **removed** are flattened flush to the **vertebral** body by the forced impaction, such as by hitting with a hammer flat

surface 109...

...absolutely parallel to the vertebral endplates, allowing optimal alignment for the procedure to be performed.

Penetrating portion 102 is available in various diameters, but all are of a constant length, which...

...preferred embodiment, a Convertible Long Distractor 113 is used on the first side of the **spine** . As shown in Figures 2, the Convertible Long Distractor 113 has a barrel portion 152...small member 116 that corresponds to threaded opening 114. The shaft 111 is prevented from **removal** from the barrel 152 by set pin 119 passing through the wall of barrel 152 in a convenient manner. The Short Distractor portion 120 is **removably** attached to the barrel portion 152 via the mating of female rectangular slot 118 and...

...to drive the crown 110 connected to interior shaft 111 having a threaded working end **screw** 116 that threads into the female aperture 118 of the Short Distractor portion 120.

Cap...

...crown 115 and engages the reduced diameter hexagonal portion 112 so as to permit the **rotation** of shaft 111 and threaded male member 116. A detent ball 150 in the inside...

...the embodiment of the Short Distractor 120 shown in Figures 3 and 3A has a **pair** of sharp pegs 126, to **embed** into the opposing vertebral bodies and forward facing ratchetings 124, that further resist backward movement ...

...to migration.

Once the ideal distraction has been achieved on the first side of the **spine** , the Convertible Distractor is dissociated, leaving Short Distractor 120 in place with its rounded external...

...As shown in Figure 4, the surgeon then moves to the other side of the **spine** at the same disc (D) level, and retracts the dural sac and nerve root medially...

...to the first side. In that event, the first side Short Distractor would then be **removed** and the Long Distractor 100 corresponding to the increased diameter of the already placed Short...

...it should be noted, that by the use of such a device as the Michelson **Spinal** Surgery Frame, it may be possible to obtain adequate distraction preoperatively such that the surgeon...

...140 is metal and has a sharp toothed front end 142 that is capable of **penetrating** into and holding fast the **two** adjacent vertebrae (V). Interrupting the circumferential sharp teeth of 142 are flat, planar areas 152...

...of the Outer Sleeve 140 is a continuation of the tubular shaft 144, which in **turn** is connected to circumferentially enlarged tubular back end 146 having a knurled outer surface 148...securing the two opposed vertebrae as shown in Figure 6.

The Cap 160 is then **removed** and the Distractor Puller 200 of Figure 9 utilized to **remove** the Long Distractor 100 from the **spine** leaving the Outer Sleeve 140 in place. The Distractor Puller 200 has front portion 202...

...inadvertent dissociation of the Long Distractor from the Puller 200 after the Distractor has been **removed** from within the Outer Sleeve 140 and prior to its **removal** from the wound. Once out of the body, the two instruments are easily disassociated by...

...force applied perpendicular to their relative long axes at this location.

A cylindrical and free **removable** weight 216 is fitted around shaft 210 between the front portion 202 and the rear...

...Distractor 100. Paired handles 224 and 226 are also useful in that they allow a **rotational** directing of portion 208, via the shaft 210. This allows the surgeon to control and manipulate rotationally the **orientation** of the opening of cavity 212 to facilitate its application, to the head 110 of...

...100.

The Distractor Puller 200 is a significant improvement over the alternatives of striking a **remover** instrument with an independent hammer over the exposed surgical wound, or manually extracting the distractor...

...by pulling is dangerous because of the significant interference fit of portion 102 within the **spine** such that significant force would be required to **remove** the Distractor 100, and if force were not coaxial then the Outer Sleeve might be **dislodged** or misaligned. Further, once the flat portion 102 became free of the interspace, all resistance to **withdrawal** would be lost and in the face of the considerable force necessary to free it...

...to the patient and/or the surgeon.

Once the Long Distractor 100 has been fully **removed** from the Outer Sleeve 140, the toothed end 142 of the Outer Sleeve 140, working...

...adjacent vertebrae V. Further, since the remainder of the procedure on that side of the **spine** occurs entirely through the protective Outer Sleeve 140, and as the nerves and dural sac...to each of the opposed vertebral surfaces.

Figure 10B is a posterior view of the **spine** at this stage of the procedure, showing a Short Distractor 120 in place on one side of the **spine** and the bottom portion of Outer Sleeve 140 in place on the opposite side of the **spine** .

Referring to Figure 11A, an Inner Sleeve 242 is inserted from the rear within the...

...and flanges engaging grooves forced therein by either a cap pulled over the flanges or **screwed** down upon them.

In the preferred embodiment, the forward cutting edge 252 of Drill 240 ...

...outside diameter of the Drill 240 corresponds to the minor diameter of the threaded spinal **implant** . The Inner Sleeve 242 has an inner diameter slightly greater than that dimension and its...

...Outer Sleeve 140 to have an internal diameter large enough to admit the threaded spinal **implant** , which is indeed considerably larger in diameter than the Drill 240 itself.

If a larger...

...wander within the confines of that greater space and would not reliably make parallel cuts **removing** equal portions of bone from the adjacent

vertebrae V. Further, the bone **removal** not only needs to be equal, but must be correctly oriented in three dimensions. That...

...the interspace.

A further purpose of the Inner Sleeve 242 is that it may be **removed** simultaneously with the Drill 240, thereby trapping the debris, both cartilaginous and bony generated during...

...and the inner wall of the Inner Sleeve 242 are there contained therein. Thus, by **removing** the Drill 240 in conjunction with the Inner Sleeve 242, all of the debris generated by the reaming procedure is safely **removed** from the **spinal** canal and wound area.

Further, if the disc tissue in the area to be reamed has been **removed** previously, as per the preferred method, then the patient's own bone of good quality...

...Once away from the surgical wound, this material may be used to load the spinal **implant** or placed deep within the interspace to participate in the fusion.

The method of actually producing the surgical hole within the **spine** is variable. As shown in Figure 11C, in an alternative embodiment Drill end 250 has hole to be formed corresponds to the minor diameter of the spinal **implant** . Trephine 270, a hollow, tubular member with sharp cutting teeth 251 at its proximal end...

...the "Trephine Method" as the bony arcs are not so much being reamed out and **removed** as they are simply being cut into the bone where these arcs of bone are...

...when the Trephining Method has been completed and the Trephine 270 and Inner Sleeve 242 **removed** , unlike in the preferred embodiment where the hole is drilled out, it remains necessary to **remove** both the two arcs of bone, and any interposed material. Nevertheless, this is very easily ...

...the perpendicularly cutting arm 278 of instrument 272 so that as handle portion 274 is **rotated** , the cutting arm 278 is also **rotated** , cutting the arcs of bone and liberating them from their last attachments. These portions of bone are then **removed** utilizing this instrument or a long forceps, and then placed within the implants or otherwise...

...participate in the fusion.

While in the preferred embodiment of the present invention the spinal **implant** I, is essentially self-tapping, if the bone is unusually hard it may be desirable to form the thread pattern within the interspace prior to the **insertion** of the **implant** I. To that end, as shown in Figure 12, Tap 280 has a threadcutting portion...

...to a handle portion 292, which has been designed to give mechanical advantage to the **rotation** of the instrument for the purpose of cutting threads. The lower portion of handle 290...

...number 1 to 8, but preferably 4, function to accumulate the bony material which is **removed** during the thread cutting process. In that regard, in the ideal embodiment, the thread cutting...

...diameter is slightly less than the major diameter of the implant.

With Tap 280 now **removed** , and Sleeve 140 still in place, the surgical site is now fully prepared to receive the spinal implant I. In the preferred embodiment of the spinal implant, the **implant** has been enhanced by the use of, application to, and filling with fusion

promoting, enhancing, and participating substances and factors. Thus, the **implant** may be fully prepared for **insertion** as provided to the operating surgeon. However, at the present time, human bone is mostand yet allows for the rapid **disconnection** of the two components once the cutting is completed.

Because of the high interference between...

...304, and the relative weakness of the cancellous bone being harvested, it is possible. to **remove** the Trephine 300 while still drilling, and to have it extract the core of bone...

...core of bone would remain fixed at its base, then with the drive mechanism 308 **removed** , a corkscrew 408 shown in Figure 14C is introduced though the central opening of rear...

...portion 306 and it can no longer advance. As corkscrew 408 is continued to be **turned** further, it will cause the core of bone to be pulled rearward, as in **removing** a cork from a wine bottle- Trephine 300 has a barrel portion 304 continuous with...

...portion 302 having an inner diameter just less than the inner diameter of the spinal **implant** I to be loaded.

The Trephine 300 with its core of harvested bone is then...

...flange 344. The plunger shaft 326 of instrument 320 is then prepared for attachment by **rotating** knob 332 counterclockwise such that the plunger 372 is pulled via the long threaded shaft...

...collar 330 are then advanced longitudinally into diametrically opposed paired L slots 340 and then **rotated** clockwise to complete this assembly.

At the other end of instrument 320, a spinal **implant** I is engaged through its female rectangular slot 364 by a rectangular protruding bar extending...

...female aperture centered within the female slot 364 of the spinal implant. With the spinal **implant** I secured to end plug 324 and the opposite end of the implant I presenting...

...open end of implant I.

As shown in Figure 15, as knob 332 is then **rotated** clockwise, the plunger 372 proximal the threaded shaft 328 is then forcibly, but controllably driven forward down the barrel 304 ejecting the bone graft directly into the spinal **implant** I. As the bone graft is greater in length than the interior of the spinal **implant** , with further compression the bone is forced into the radially disposed apertures through the wall...

...the device communicating from the central cavity to the exterior.

End plug 324 is then **removed** from apparatus 320. Using end plug 324 as a handle, end cap 374 shown in Figure 16 is secured to the open end of the spinal **implant** I. The **implant** is then disassociated from end plug 324 by **rotating** knob 334 counterclockwise.

Figure 16 shows an Implant Driver instrument which may be used to either **insert** or to **remove** said **implant** I. Driver 350 has at its far end 362, a rectangular protrusion 398, which protrusion...

...hand barrel 360 to knob 354 where it can be rotationally controlled. Threaded portion 353 **screws** into a female aperture central slot 364, urging 353 into 364, and binding them together such that instrument 350

can be **rotated** via paired and diametrically opposed extending arms 366 and in either direction while maintaining contact with the implant.

Affixed to the Driver 350, the **implant** is then **introduced** through the Outer Sleeve 140 and **screwed** into the interspace opposed between the two prepared **vertebrae** V until such time as the leading edge of the **Implant** Cap 374 reaches the depth of the prepared hole at which time its forward motion...

...drilled out. This allows for a progressive feel to the surgeon as the implant is **screwed** home.

As described previously, with the use of the Tap 280, this terminal resistance to...

...to the surgeon. Again, as with the Tap 280, visual monitoring of the depth of **insertion** of the **implant** is provided to the surgeon by observing the progressive approximation of the forward surface 370 prohibiting any further installation of the spinal **implant** .

Once the **implant** has been fully installed, the Driver 350 is dissociated from the implant by **turning** knob 354 in a counterclockwise direction. The Driver 350 is then **withdrawn** from the outer sheath, then the Outer Sleeve 140 is **removed** . This leaves the **implant** fully installed and inset to the determined depth as shown in Figure 18.

Attention is then redirected to the other, or first, side of the **spine** . A dural nerve root retractor is used to retract the neural structures -medially, bringing into...

...of the Short Distractor 120, lying flush on the canal floor. Utilizing apparatus 152, extended **screw** portion 116 is inserted into the female threaded portion 114 of the Short Distractor 120...

...152 is engaged to the female rectangular portion 118 of the Short Distractor 120. Then **turning** rearward facing portions 108 and 110, utilizing the knob 136 of Figure 2, the Long...

...implantation of the spinal implant I as already placed, is then repeated such that both **spinal** **implants** come to lie side by side within the interspace. Though not necessary, circlage or other...

...Predistraction And Utilizing A Guarded Sleeve System Is Disclosed

Because of the absence of the **spinal** cord and nerve roots, it is generally possible to visualize in one instance the entire width of the disc space from side to side throughout the cervical, thoracic, or lumbar **spine** . In the preferred embodiment of the anterior interbody fusion, **implants** are placed side by side from anterior to posterior parallel to the interspace and extending...

...the transverse width of the disc space is insufficient to allow for the use of **two** **implants** , each of which would be large enough to protrude to the required depth into the adjacent **vertebrae** , then a singular and significantly larger **implant** may be placed centrally. With this in mind, and in light of the very detailed...

...in regard to the method of posterior lumbar interbody fusion, a brief discussion of anterior **spinal** interbody fusion with dual **implant** installation will suffice, and the method for installation of a large, singular midline graft will become obvious.

The interspace to be fused is exposed anteriorly. The soft tissues are **withdrawn** and protected to either side, and if necessary, above and below as well. It is...

...great bulk of the nuclear disc portion. (Alternatively, the disc can be left to be **removed** via the drill later.) The surgeon then notes and marks a point midway from side to side anteriorly. He then **inserts** Long Distractor 100 centering it on a point midway between the point just noted and...

...Distractor 100 producing the ideal interspace distraction having its barrel portion 106 corresponding to the **implant** to be installed has been **inserted** , then its exact duplicate is inserted anteriorly equidistant to the other side of the **spine** . As the barrel portion 106 of Long Distractor 100 is exactly of the same major diameter as the spinal **implant** I looking coaxially on end, the surgeon can then asses theanticipated side by side relationship...

...As shown in Figures 7C and 7D, a Dual Outer Sleeve 340 consisting of a **pair** of hollow tubes is then **introduced** over the side by side Long Distractors protruding anteriorly from the **spine** . The Dual Outer Sleeve 340 is comprised of two hollow tubular members identical in size **displaced** from each other ideally the sum of the difference between the minor and major diameters of **both** **implants** combined, but not less than that difference for one implant, as it is possible to...

...slightly greater than two times the difference between the major and minor diameters of the **implant** (the sum of **both**) the distance may be considerably greater. Whereas in the preferred embodiment extending tubular portions 348...

...may be inclined or declined relative to each other such that they either converge or **diverge** at their proximal ends. Paired tubular structures 348, may be bridged in part or wholly...

...rigidly held via Foot Plate 344 and the prongs 342. Thus, it is possible to **remove** either one, or if desired, both of the Long Distractor rods utilizing Long Distractor puller...

...is then the surgeon's choice to work on one or both sides of the **spine** . As per previous discussion, the surgeon may drill the interspace utilizing the Inner Sleeve 242...

...the Long Distractors in place as per the "Trephine Method".
Tapping, if necessary, and the **insertion** of the **implants** then occurs through the protective Outer Sleeve 340. Once the **implants** have been fully **inserted** , the Outer Sleeve is **removed** .
Having utilized the Drill method, or "Trephine Method", with or without an Inner Sleeve to...

...the interspace, or preferring the ability to directly visualize the tap being used, or the **implant** being **inserted** , may choose to **remove** the Outer Sleeve after the insertion of the first prosthesis to maintain stability, or prior...

...Preferred Embodiment For Method Of Anterior Interbody Fusion
As previously described for the posterior lumbar **spine** , alternatively, one can employ the "Trephine Method" as has been described in detail.
As a...

...the preferred embodiment, it is nevertheless within the scope of this invention that one could **remove** the Outer Sleeve as there are no neural structures requiring protection, and **insert** the **implants** directly

rather than through the Outer Sleeve.

As yet a further alternative of this method...

...depth into the opposed vertebral bodies is such that it is not possible to place **two** such **implants** side by side, then only a single implant which may be of significantly increased diameter...

...or the "Trephine Method".

Referring to Figures 16-18, a cylindrical embodiment of the spinal **implant** I of the present invention is shown. In Figure 16 the implant I is shown...

...I is shown installed in the disc space D, between the adjacent vertebrae.

The cylindrical **implant** I comprises a hollow tubular member which in the preferred embodiment is made of an...While the present invention has been described in association with the implant of a threaded **spinal** implant, it is recognized that other forms of **implants** may be used with the present method. For example, dowels, made from bone or artificial materials, knurled or irregularly shaped cylinders or spheres, or any other shaped **implants** that can be **introduced** through the outer sleeve may be used. Being able to perform the procedure through the...

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DIALOG(R)File 348:EUROPEAN PATENTS

00675406
APPARATUS FOR INSERTING SPINAL IMPLANTS
GERAT ZUM EINSETZEN VON RUCKENWIRBELIMPLANTATEN
APPAREIL D' INSERTION **D'** IMPLANTS SPINAUX
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Available Text	Language	Update	Word Count
CLAIMS B	(English)	200335	574
CLAIMS B	(German)	200335	568
CLAIMS B	(French)	200335	607
SPEC B	(English)	200335	14837
Total word count - document A			0
Total word count - document B			16586
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APPAREIL D' INSERTION **D'** IMPLANTS SPINAUX
INTERNATIONAL PATENT CLASS: **A61B-017/16** ...

... **A61B-017/02** ...
... **A61B-017/32**

...SPECIFICATION only the Long Distractor prior to repeating the procedure on the contralateral side of the **spine** . While this method can be performed in accordance with the remaining steps as described above...

...later.
Step 5. With the Short Distractor in place on the first side of the **spine** , and the matching Long Distractor in place on the second side of the **spine** , and with the ducal sac and traversing nerve root safely retracted, the Outer Sleeve is...

...its optimal depth using the Impaction cap and a mallet. The Long

Distractor is then **removed** .

Step 6. An Inner Sleeve is then placed within the Outer Sleeve, and the interspace...

...Drill, Endmill, Reamer, or Trephine to drill, ream, or cut out the bone to be **removed** to either side, as well as any remaining interposed discal material. Utilizing a specially designed Endmill-Drill, it and the Inner Sleeve are **removed** as a unit, safely carrying away the bone and disc debris trapped within them from the **spinal** canal.

Step 7. If required, a thread forming Tap with penetration limiting means to control the depth of insertion, is then inserted through the Outer Sleeve.

Step 8. The prepared **implant** is then **inserted** utilizing the specialized Driver unit. It should be noted that the implant may be coated...

...than the inside diameter of the spinal implant to be loaded, but longer than the **spinal implant** . Utilizing an instrument designed for that purpose, the core of bone is then injected from...

...Driver Extractor instrument, the prepared implant is threaded into the prepared interspace. The instrumentation is **removed** from that side of the **spine** and attention is then redirected to the first side of the **spine** . A small retractor is utilized to move the dural sac and traversing nerve root medially...

...to protect them and allowing the direct visualization of the retained Short Distractor unit. Without **removing** the Short Distractor, it is reassembled to its shaft portion, essentially reconstituting itself into a Long Distractor. With the **inserted implant** now acting as the distractor on the opposite side, the Long Distractor is utilized to...

...while a Long Distractor having an outside diameter to the barrel portion corresponding to the **implant** to be **inserted** , that is 18mm, and having a diameter at the working end of perhaps 8mm, would...

...the ideal distraction, the Convertible Distractor would then be disassembled, the barrel and head portion **removed** , and the Short Distractor portion left deeply embedded and with its flanged head flat against...

...and driven flush to the bone if necessary, such impaction imploding any osteophytes not already **removed** , and assuring that the shoulder portion of the barrel comes to lie flat against the...

...Driver Cap and a mallet, seated to the optimal depth.

The Long Distractor is then **removed** and the Inner Sleeve is inserted into the Outer Sleeve. Since the purpose of the...

...of the implant over the size of the drill, thus making it possible for the **insertion** of the **implant** to occur through the Outer Sleeve, the Inner Sleeve therefore measures 18mm in its outside...

...is 16.5mm in diameter.

Following the drilling procedure, the Drill and Inner Sleeve are **removed** as a single unit with the trapped interposed cartilaginous and bony debris. The depth of...

...inserted at this time and be appropriate to the minor and major diameters of the **implant** to be **inserted** and as with the Drill, controlled for its depth of penetration. The **spinal implant** would

then be prepared for implantation by utilizing a Trephine to harvest a core of...

...this core of bone would be forcefully injected into the internal chamber of the spinal **implant** which would then be capped. Cap end forward, the fully loaded implant would then be attached to the Insertion Driver, down the Outer Sleeve and **screwed** into place with the depth of penetration limited by the Insertion instrument. The Insertion Driver is then unscrewed from the implant and **removed** from the Outer Sleeve. With the dural sac and nerve root retracted and protected, the Outer Sleeve would then be **removed** . This would complete the fusion procedure on that side, and then as described, the procedure...

...on the opposite side, and while nevertheless maintaining distraction at the site of the bone **removal** .

The following is a description of the "Trephine Method".

Having completed the exposure of the...only in that the barrel portion is of a precisely lesser diameter than the spinal **implant** . As in the Representative Example, the Outer Sleeve has an inner diameter only slightly greater than the **implant** to be **inserted** . Therefore, at this time, a first Inner Sleeve is inserted into the Outer Sleeve to...

...Sleeve is optimally seated using the Impaction Cap. The Cap and first Inner Sleeve are **removed** , but the Long Distractor and Outer Sleeve are left in place.

With the Long Distractor...

...methods, the Trephine, the Long Distractor, and the second Inner Sleeve, if utilized, are all **removed** . Since the Trephine cuts two arcs of bone but does not ream them out, a...

...portion at its working end is then inserted parallel to the disc space and then **rotated** through an arc of motion cutting the bases of the two longitudinally cut arcs, thus freeing them for **removal** through the Outer Sleeve. The space may then be tapped if required, and the implant is inserted as per the preferred **method** . As already mentioned, the "Trephine Method" can be used with or without the use of the Short Distractor on the contralateral side.

Applications in Other Areas of the **Spine**

The following is for performing anterior interbody fusion in the thoracic and lumbar **spines** . It is also appropriate in the cervical **spine** when the width of the **spine** anteriorly is sufficient so that it is possible to place **two** **implants** side by side and such that each intrudes at least several millimeters into the substance of the opposed **vertebrae** and for the length of the **implants** .

The interspace to be fused is adequately exposed and the soft tissues and vital structures...

...possible by the absence of the neurological structures in relation to this aspect of the **spine** . The center line of the anterior aspect of the interspace is noted and marked. The disc is **removed** using first a knife and then curettes and rongeurs as needed. Alternatively, the disc may be left intact to be **removed** during the drilling stage of the procedure. However, as per the preferred embodiment of the procedure, having **removed** the great mass of the nucleus and the greater portion of the annulus anteriorly, Long...

...between the central marking line and the lateral extent of the anterior aspect of the **spine** as visualized.

The Dual Outer Sleeve with its common Foot Plate and Retention Prongs is...

...placed. The Dual Outer Sleeve is then seated firmly against the anterior aspect of the **spine** . Any spurs which would interfere with the flush seating of the Foot Plate to the anterior aspect of the **spine** should be **removed** prior to inserting the Long Distractors. Once the Outer Sleeve has been optimally seated, one of the Long Distractors is **removed** and in its place is inserted an Inner Sleeve and drill bit. The drill bit has as its outside diameter the minor diameter of the **implant** to be **inserted** . The Inner Sleeve is essentially equal in thickness to the difference between the minor and major diameters of the threaded **implant** .

A Stopped Drill is then utilized to prepare the opposed vertebral surfaces and to **remove** any remaining disc material interposed. If required, a Stopped Tap may be inserted through the Outer Sleeve and into the interspace to create a thread form. The properly prepared **implant** is then affixed to the **Insertion** Driver and passed through the Outer Sleeve down into the interspace and inserted until its depth of penetration is limited by the stop on the **Insertion** Driver. With the **implant** itself now in a **position** to act as a distractor, the Long Distractor is then **removed** from the contralateral side and the procedure repeated. When **both implants** are firmly in place, the outer sleeve may then be **removed** . The amount of countersinking of the implants may then be adjusted under direct vision.

Detailed...

...bilateral paired semihemilaminotomies of the adjacent vertebrae. Preferably the supraspinous ligament, the interspinous ligament, the **spinous** process, portions of the lamina, and most of the facet joints are preserved. However, while less desirable, these structures may be **removed** .

A bilateral partial nuclear discectomy is then performed through bilateral openings created through the posterior...

...adjacent vertebral bodies and the interposed disc posteriorly.

Referring now to Figure 1, preferably after **removing** some portion of nuclear disc material, a Long Distractor 100 is inserted under direct vision...

...bone of the posterior vertebral bodies adjacent the posterior disc which have not already been **removed** are flattened flush to the **vertebral** body by the forced impaction, such as by hitting with a hammer flat surface 109...

...absolutely parallel to the vertebral endplates, allowing optimal alignment for the procedure to be performed.

Penetrating portion 102 is available in various diameters, but all are of a constant length, which...

...Figure 9.

A Convertible Long Distractor 113 is used on the first side of the **spine** . As shown in Figures 2, the Convertible Long Distractor 113 has a barrel portion 152...

...small member 116 that corresponds to threaded opening 114. The shaft 111 is prevented from **removal** from the barrel 152 by set pin 119 passing through the wall of barrel 152 in a convenient manner. The Short Distractor portion 120 is **removably** attached to the barrel portion 152

via the mating of female rectangular slot 118 and...

...to drive the crown 110 connected to interior shaft 111 having a threaded working end **screw** 116 that threads into the female aperture 118 of the Short Distractor portion 120.

Cap...

...crown 115 and engages the reduced diameter hexagonal portion 112 so as to permit the **rotation** of shaft 111 and threaded male member 116. A detent ball 150 in the inside...

...the embodiment of the Short Distractor 120 shown in Figures 3 and 3A has a **pair** of sharp pegs 126, to **embed** into the opposing vertebral bodies and forward facing ratchetings 124, that further resist backward movement ...

...to migration.

Once the ideal distraction has been achieved on the first side of the **spine** , the Convertible Distractor is dissociated, leaving Short Distractor 120 in place with its rounded external Figure 4, the surgeon then moves to the other side of the **spine** at the same disc (D) level, and retracts the dural sac and nerve root medially...

...to the first side. In that event, the first side Short Distractor would then be **removed** and the Long Distractor 100 corresponding to the increased diameter of the already placed Short...

...it should be noted, that by the use of such a device as the Michelson **Spinal** Surgery Frame, it may be possible to obtain adequate distraction preoperatively such that the surgeon...

...140 is metal and has a sharp toothed front end 142 that is capable of **penetrating** into and holding fast the **two** adjacent vertebrae (V). Interrupting the circumferential sharp teeth of 142 are flat, planar areas 152...

...of the Outer Sleeve 140 is a continuation of the tubular shaft 144, which in **turn** is connected to circumferentially enlarged tubular back end 146 having a knurled outer surface 148...

...securing the two opposed vertebrae as shown in Figure 6.

The Cap 160 is then **removed** and the Distractor Puller 200 of Figure 9 utilized to **remove** the Long Distractor 100 from the **spine** leaving the Outer Sleeve 140 in place. The Distractor Puller 200 has front portion 202...

...inadvertent dissociation of the Long Distractor from the Puller 200 after the Distractor has been **removed** from within the Outer Sleeve 140 and prior to its **removal** from the wound. Once out of the body, the two instruments are easily disassociated by...force applied perpendicular to their relative long axes at this location.

A cylindrical and free **removable** weight 216 is fitted around shaft 210 between the front portion 202 and the rear...

...Distractor 100. Paired handles 224 and 226 are also useful in that they allow a **rotational** directing of portion 208, via the shaft 210. This allows the surgeon to control and manipulate rotationally the **orientation** of the opening of cavity 212 to facilitate its application, to the head 110 of...

...100.

The Distractor Puller 200 is a significant improvement over the alternatives of striking a **remover** instrument with an independent hammer over the exposed surgical wound, or manually extracting the distractor...

...by pulling is dangerous because of the significant interference fit of portion 102 within the **spine** such that significant force would be required to **remove** the Distractor 100, and if force were not coaxial then the Outer Sleeve might be **dislodged** or misaligned. Further, once the flat portion 102 became free of the interspace, all resistance to **withdrawal** would be lost and in the face of the considerable force necessary to free it...

...to the patient and/or the surgeon.

Once the Long Distractor 100 has been fully **removed** from the Outer Sleeve 140, the toothed end 142 of the Outer Sleeve 140, working...

...adjacent vertebrae V. Further, since the remainder of the procedure on that side of the **spine** occurs entirely through the protective Outer Sleeve 140, and as the nerves and dural sac...

...to each of the opposed vertebral surfaces.

Figure 10B is a posterior view of the **spine** at this stage of the procedure, showing a Short Distractor 120 in place on one side of the **spine** and the bottom portion of Outer Sleeve 140 in place on the opposite side of the **spine** .

Referring to Figure 11A, an Inner Sleeve 242 is inserted from the rear within the...

...and flanges engaging grooves forced therein by either a cap pulled over the flanges or **screwed** down upon them.

The forward cutting edge 252 of Drill 240 is a modification of...

...outside diameter of the Drill 240 corresponds to the minor diameter of the threaded spinal **implant** . The Inner Sleeve 242 has an inner diameter slightly greater than that dimension and its an internal diameter large enough to admit the threaded spinal **implant** , which is indeed considerably larger in diameter than the Drill 240 itself.

If a larger...

...wander within the confines of that greater space and would not reliably make parallel cuts **removing** equal portions of bone from the adjacent vertebrae V. Further, the bone **removal** not only needs to be equal, but must be correctly oriented in three dimensions. That...

...the interspace.

A further purpose of the Inner Sleeve 242 is that it may be **removed** simultaneously with the Drill 240, thereby trapping the debris, both cartilaginous and bony generated during...

...and the inner wall of the Inner Sleeve 242 are there contained therein. Thus, by **removing** the Drill 240 in conjunction with the Inner Sleeve 242, all of the debris generated by the reaming procedure is safely **removed** from the **spinal** canal and wound area.

Further, if the disc tissue in the area to be reamed has been **removed** previously, as per the preferred method, then the patient's own bone of good quality...

...Once away from the surgical wound, this material may be used to load the spinal **implant** or placed deep within the interspace to participate in the fusion.

The method of actually producing the surgical hole within the **spine** is variable. Figure 11C, shows an alternative Drill end 250 which has a forward projecting...

...the method, the hole to be formed corresponds to the minor diameter of the spinal **implant** . Trephine 270, a hollow, tubular member with sharp cutting teeth 251 at its proximal end...

...the "Trephine Method" as the bony arcs are not so much being reamed out and **removed** as they are simply being cut into the bone where these arcs of bone are...

...when the Trephining Method has been completed and the Trephine 270 and Inner Sleeve 242 **removed** , unlike where the hole is drilled out, it remains necessary to **remove** both the two arcs of bone, and any interposed material. Nevertheless, this is very easily...

...the perpendicularly cutting arm 278 of instrument 272 so that as handle portion 274 is **rotated** , the cutting arm 278 is also **rotated** , cutting the arcs of bone and liberating them from their last attachments. These portions of bone are then **removed** utilizing this instrument or a long forceps, and then placed within the implants or otherwise used to participate in the fusion.

While the spinal **implant** I, is essentially self-tapping, if the bone is unusually hard it may be desirable to' form the thread pattern within the interspace prior to the **insertion** of the **implant** I. To that end, as shown in Figure 12, Tap 280 has a threadcutting portion...

...to a handle portion 292, which has been designed to give mechanical advantage to the **rotation** of the instrument for the purpose of cutting threads. The lower portion of handle 290...number 1 to 8, but preferably 4, function to accumulate the bony material which is **removed** during the thread cutting process. In that regard, the thread cutting form is designed to...

...diameter is slightly less than the major diameter of the implant.

With Tap 280 now **removed** , and Sleeve 140 still in place, the surgical site is now fully prepared to receive the spinal **implant** I. The **implant** has been enhanced by the use of, application to, and filling with fusion promoting, enhancing, and participating substances and factors. Thus, the **implant** may be fully prepared for **insertion** as provided to the operating surgeon. However, at the present time, human bone is most...

...mechanism 312 is stable during the clockwise cutting procedure, and yet allows for the rapid **disconnection** of the two components once the cutting is completed.

Because of the high interference between...

...304, and the relative weakness of the cancellous bone being harvested, it is possible to **remove** the Trephine 300 while still drilling, and to have it extract the core of bone...

...core of bone would remain fixed at its base, then with the drive mechanism 308 **removed** , a corkscrew 408 shown in Figure 14C is introduced though the central opening of rear...

...portion 306 and it can no longer advance. As corkscrew 408 is continued to be **turned** further, it will cause the core of bone to be pulled rearward, as in **removing** a cork from a wine bottle. Trephine 300 has a barrel portion 304 continuous with...

...portion 302 having an inner diameter just less than the inner diameter of the spinal **implant** I to be loaded.

The Trephine 300 with its core of harvested bone is then...

...flange 344. The plunger shaft 326 of instrument 320 is then prepared for attachment by **rotating** knob 332 counterclockwise such that the plunger 372 is pulled via the long threaded shaft...

...collar 330 are then advanced longitudinally into diametrically opposed paired L slots 340 and then **rotated** clockwise to complete this assembly.

At the other end of instrument 320, a spinal **implant** I is engaged through its female rectangular slot 364 by a rectangular protruding bar extending...

...female aperture centered within the female slot 364 of the spinal implant. With the spinal **implant** I secured to end plug 324 and the opposite end of the implant I presenting...open end of implant I.

As shown in Figure 15, as knob 332 is then **rotated** clockwise, the plunger 372 proximal the threaded shaft 328 is then forcibly, but controllably driven forward down the barrel 304 ejecting the bone graft directly into the spinal **implant** I. As the bone graft is greater in length than the interior of the spinal **implant** , with further compression the bone is forced into the radially disposed apertures through the wall...

...the device communicating from the central cavity to the exterior.

End plug 324 is then **removed** from apparatus 320. Using end plug 324 as a handle, end cap 374 shown in Figure 16 is secured to the open end of the spinal **implant** I. The **implant** is then disassociated from end plug 324 by **rotating** knob 334 counterclockwise.

Figure 16 shows an Implant Driver instrument which may be used to either **insert** or to **remove** said **implant** I. Driver 350 has at its far end 362, a rectangular protrusion 398, which protrusion...

...hand barrel 360 to knob 354 where it can be rotationally controlled. Threaded portion 353 **screws** into a female aperture central slot 364, urging 353 into 364, and binding them together such that instrument 350 can be **rotated** via paired and diametrically opposed extending arms 366 and in either direction while maintaining contact with the implant.

Affixed to the Driver 350, the **implant** is then **introduced** through the Outer Sleeve 140 and **screwed** into the interspace opposed between the two prepared **vertebrae** V until such time as the leading edge of the **Implant** Cap 374 reaches the depth of the prepared hole at which time its forward motion...

...drilled out. This allows for a progressive feel to the surgeon as the implant is **screwed** home.

As described previously, with the use of the Tap 280, this terminal resistance to...

...to the surgeon. Again, as with the Tap 280, visual monitoring of the depth of **insertion** of the **implant** is provided to the surgeon by observing the progressive approximation of the forward surface 370...

...abut surface 172 of the Outer Sleeve 140, prohibiting any further installation of the spinal **implant** .

Once the **implant** has been fully installed, the Driver 350 is dissociated from the implant by **turning** knob 354 in a counterclockwise direction. The Driver 350 is then **withdrawn** from the outer sheath, then

the Outer Sleeve 140 is **removed** . This leaves the **implant** fully installed and inset to the determined depth as shown in Figure 18.

Attention is then redirected to the other, or first, side of the **spine** . A dural nerve root retractor is used to retract the neural structures medially, bringing into...

...of the Short Distractor 120, lying flush on the canal floor. Utilizing apparatus 152, extended **screw** portion 116 is inserted into the female threaded portion 114 of the Short Distractor 120...

...152 is engaged to the female rectangular portion 118 of the Short Distractor 120. Then **turning** rearward facing portions 108 and 110, utilizing the knob 136 of Figure 2, the Long...

...implantation of the spinal implant I as already placed, is then repeated such that both **spinal** implants come to lie side by side within the interspace. Though not necessary, circlage or other...

...Predistraction And Utilizing A Guarded Sleeve System Is Disclosed

Because of the absence of the **spinal** cord and nerve roots, it is generally possible to visualize in one instance the entire width of the disc space from side to side throughout the cervical, thoracic, or lumbar **spine** . In the anterior interbody fusion, **implants** are placed side by side from anterior to posterior parallel to the interspace and extending ...

...the transverse width of the disc space is insufficient to allow for the use of **two** **implants** , each of which would be large enough to protrude to the required depth into the adjacent **vertebrae** , then a singular and significantly larger **implant** may be placed centrally. With this in mind, and in light of the very detailed...

...instrumentation already provided in regard to posterior lumbar interbody fusion, a brief discussion of anterior **spinal** interbody fusion with dual **implant** installation will suffice, and installation of a large, singular midline graft will become obvious.

The interspace to be fused is exposed anteriorly. The soft tissues are **withdrawn** and protected to either side, and if necessary, above and below as well. It is...

...great bulk of the nuclear disc portion. (Alternatively, the disc can be left to be **removed** via the drill later.) The surgeon then notes and marks a point midway from side to side anteriorly. He then **inserts** Long Distractor 100 centering it ...Distractor 100 producing the ideal interspace distraction having its barrel portion 106 corresponding to the **implant** to be installed has been **inserted** , then its exact duplicate is inserted anteriorly equidistant to the other side of the **spine** . As the barrel portion 106 of Long Distractor 100 is exactly of the same major diameter as the spinal **implant** I looking coaxially on end, the surgeon can then asses the anticipated side by side...

...As shown in Figures 7C and 7D, a Dual Outer Sleeve 340 consisting of a **pair** of hollow tubes is then **introduced** over the side by side Long Distractors protruding anteriorly from the **spine** . The Dual Outer Sleeve 340 is comprised of two hollow tubular members identical in size **displaced** from each other ideally the sum of the difference between the minor and major diameters of **both** **implants** combined, but not less than that difference for one implant, as it is possible to...

...common area between them. However, the difference between the major and minor diameters of the **implant** (the sum of **both**) the distance may be considerably greater. Whereas extending tubular portions 348 of

instrument 340 are...

...may be inclined or declined relative to each other such that they either converge or **diverge** at their proximal ends. Paired tubular structures 348, may be bridged in part or wholly...

...rigidly held via Foot Plate 344 and the prongs 342. Thus, it is possible to **remove** either one, or if desired, both of the Long Distractor rods utilizing Long Distractor puller...

...is then the surgeon's choice to work on one or both sides of the **spine** . As per previous discussion, the surgeon may drill the interspace utilizing the Inner Sleeve 242...

...the Long Distractors in place as per the "Trephine Method".
Tapping, if necessary, and the **insertion** of the **implants** then occurs through the protective Outer Sleeve 340. Once the **implants** have been fully **inserted** , the Outer Sleeve is **removed** .
Having utilized the Drill method, or "Trephine Method", with or without an Inner Sleeve to...the interspace, or preferring the ability to directly visualize the tap being used, or the **implant** being **inserted** , may choose to **remove** the Outer Sleeve after the insertion of the first prosthesis to maintain stability.
In anterior...

...depth into the opposed vertebral bodies is such that it is not possible to place **two** such **implants** side by side, then only a single implant which may be of significantly increased diameter...

...or the "Trephine Method".
Referring to Figures 16-18, a cylindrical embodiment of the spinal **implant** I of the present invention is shown. In Figure 16 the implant I is shown...
...I is shown installed in the disc space D, between the adjacent vertebrae.
The cylindrical **implant** I comprises a hollow tubular member which in the preferred embodiment is made of an...

...While the present invention has been described in association with the implant of a threaded **spinal** implant, it is recognized that other forms of **implants** may be used. For example, dowels, made from bone or artificial materials, knurled or irregularly shaped cylinders or spheres, or any other shaped **implants** that can be **introduced** through the outer sleeve may be used. Being able to perform the procedure through the...

...CLAIMS reponse a une distraction supplementaire des corps vertebraux adjacents pendant l'insertion de l'implant **spinal** dans l'espace d'implantation.
7. Appareil selon la revendication 6, comprenant en outre une...

...insertion (350) configure pour fixer ledit implant (I) et installer ledit implant (I) entre les **vertebres** adjacentes (V).

34/3,K/14 (Item 14 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00280646
APPARATUS AND METHOD OF INSERTING SPINAL IMPLANTS
APPAREIL ET PROCEDE D'INSERTION D'IMPLANTS SPINAUX
Patent Applicant/Assignee:
KARLIN TECHNOLOGY INC,
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Detailed Description
Claims
Detailed Description
... and flanges engaging grooves forced therein by either a cap pulled over the flanges or **screwed** down upon them.

In the preferred embodiment, the forward cutting edge 252 of Drill 240...

...The outside diameter of the Drill 240 corresponds to the minor diameter of the threaded **spinal implant** . The Inner Sleeve 242 has an inner diameter slightly greater than that dimension and its...

...the Outer Sleeve 140 to have an internal diameter large enough to admit the threaded **spinal implant** ,, which is indeed considerably larger in diameter than the Drill 240 itself.

If a larger...

....wander within the confines of that greater space and would not reliably make parallel cuts **removing** equal portions of bone from the adjacent vertebrae V. Further,, the bone **removal** not only needs to be equal, but must be correctly oriented in three dimensions. That...

...the interspace, A further purpose of the Inner Sleeve 242 is that it may be **removed** simultaneously with the Drill 240,, thereby trapping the debris, both cartilaginous and bony generated during...

...and the inner wall of the Inner Sleeve 242 are there contained therein, Thus,, by **removing** the Drill 240 in conjunction with the Inner Sleeve 242, all of the debris generated by the reaming procedure

is safely **removed** from the **spinal** canal and wound area, Further,, if the disc tissue in the area to be reamed has been **removed** previously, as per the preferred method, then the patient's own bone of good quality...256, Once away from the surgical wound, this material may be used to load the **spinal** **implant** or placed deep within the interspace to participate in the fusion.
The method of actually producing the surgical hole within the **spine** is variable. As shown in Figure 11C, in an alternative embodiment Drill end 250 has...

...of the method,, the hole to be formed corresponds to the minor diameter of the **spinal** **implant** . Trephine 270, a hollow, tubular member with sharp cutting teeth 251 at its proximal end...

...the "Trephine Method" as the bony arcs are not so much being reamed out and **removed** as they are simply being cut into the bone where these arcs of bone are...

...when the Trephining Method has been completed and the Trephine 270 and Inner Sleeve 242 **removed** , unlike in the preferred embodiment where the hole is drilled out, it remains
SUBSTITUTI, E- SHEET (RULE 26)
necessary to **remove** both the two arcs of bone, and any interposed material. Nevertheless,, this is very easily...the perpendicularly cutting arm 278 of instrument 272 so that as handle portion 274 is **rotated** , the cutting arm 278 is also **rotated** , cutting the arcs of bone and liberating them from their last attachments.

These portions of bone are then **removed** utilizing this instrument or a long forceps, and then placed within the implants or otherwise...

...to participate in the fusion.

While in the preferred embodiment of the present invention the **spinal** **implant** I0, is essentially self-tapping, if the bone is unusually- hard it may be desirable to form the thread pattern within the interspace prior to the **insertion** of the **implant** I, To that end, as shown in Figure 12, Tap 280 has a threadcutting portion...

...to a handle portion 292, which has been designed to give mechanical advantage to the **rotation** of the instrument for the purpose of cutting threads, The lower portion of handle 290...
...number I to 8, but preferably 4, function to accumulate the bony material which is **removed** during the thread cutting process, In that regard, in the ideal embodiment, the thread cutting...diameter is slightly less than the major diameter of the implant.

With Tap 280 now **removed** , and Sleeve 140 still in place, the surgical site is now fully prepared to receive the **spinal** implant I. In the preferred embodiment of the

spinal implant, the **implant** has been enhanced by the use of , application to, and filling with fusion promoting, enhancing, and participating substances and factors, Thus, the **implant** may be fully prepared for **insertion** as provided to the operating surgeon, However, at the present time, human bone is most...

...during
the clockwise cutting procedure, and yet allows for the SUBSTITUTE SHEET (RULE 26)
rapid **disconnection** of the two components once the cutting is completed,
Because of the high interference between...
...304, and the
relative weakness of the cancellous bone being harvested, it is possible to **remove** the Trephine 300 while still drilling, and to have it extract the core of bone with it, However, in the highly unlikely event that the core of bone mechanism 308 **removed** , a corkscrew 408 shown in Figure 14C is introduced though the central opening of rear...

...portion 306 and it can no longer advance. As corkscrew 408 is continued to be- **turned** further, it will cause the core of bone to be pulled rearward, as in **removing** a cork from a wine bottle, Trephine 300 has a barrel portion 304 continuous with...

...toothed portion 302 having an inner
diameter just less than the inner diameter of the **spinal implant** I to be loaded,
The Trephine 300 with its core of harvested bone is then 344, The plunger shaft 326 of instrument 320 is then prepared for attachment by **rotating** knob 332 counterclockwise such that the plunger 372 is pulled via the long threaded shaft...
...collar 330 are then advanced
longitudinally into diametrically opposed paired L slots 340 and then **rotated** clockwise to complete this assembly, At the other end of instrument 320,, a **spinal implant** I is engaged through its female rectangular slot 364 by a rectangular protruding bar extending...

...a female aperture centered
within the female slot 364 of the spinal implant, With the **spinal implant** I secured to end plug 324 and the opposite end of the implant I presenting...

...open
end of implant I.

As shown in Figure 15, as knob 332 is then **rotated** clockwise, the plunger 372 proximal the threaded shaft 328 is then forcibly, but controllably driven forward down the barrel 304 ejecting the bone graft directly into the **spinal implant** I, As the bone graf t is greater in length than the interior of the **spinal implant** , with further compression the bone is f orced into the radially disposed apertures through the...

...the device

communicating from the central cavity to the exterior,
End plug 324 is then **removed** from apparatus 320,
Using end plug 324 as a handle, end cap 374 shown in Figure 16 is secured to the open end of the **spinal implant** I, The **implant** is then disassociated from end plug 324 by **rotating** knob 334 counterclockwise,
Figure 16 shows an Implant Driver instrument
which may be used to either **insert** or to **remove** said, **implant** I. Driver 350 has at its far end 362, a
rectangular protrusion 398,, which protrusion knob 354 where it can be
rotationally controlled, Threaded portion 353 **screws** into
a female aperture central slot 364, urging 353 into 364,
SUBSTITUTE SHEET 'RULE 26)
and binding them together such that instrument 350 can be **rotated** via paired and diametrically opposed extending arms 366 and in either direction while maintaining contact with the implant.

Affixed to the Driver 350, the **implant** is then **introduced** through the Outer Sleeve 140 and **screwed** into the interspace opposed between the two prepared **vertebrae** V until such time as the leading edge of the **Implant** Cap 374 reaches the depth of the prepared hole at which time its forward motion...

...drilled out. This allows for a
progressive feel to the surgeon as the implant is **screwed** home,
As described previously, with the use of the Tap 280, this terminal resistance to...

...to the surgeon. Again, as
with the Tap 280, visual monitoring of the depth of **insertion** of the **implant** is provided to the surgeon by observing the progressive approximation of the forward surface 370...

...will abut surface 172 of the Outer Sleeve 140,
prohibiting any further installation of the **spinal implant** .

Once the **implant** has been fully installed, the
Driver 350 is dissociated from the implant by **turning** knob 354 in a counterclockwise direction. The Driver 350 is
SUBSTITUTE SHEE-Dr
then **withdrawn** from the outer sheath, then the outer Sleeve 140 is **removed** , This leaves the **implant** fully installed and inset to the determined depth as shown in Figure 18.

Attention is then redirected to the other, or
first, side of the **spine** . A dural nerve root retractor is.

used to retract the neural structures medially, bringing into...

...of the Short Distractor 120,
lying flush on the canal floor, Utilizing apparatus 152,
extended **screw** portion 116 is inserted into the female threaded portion 114 of the Short Distractor 120...

...152 is

engaged to the female rectangular portion 118 of the Short Distractor 120, Then **turning** rearward facing portions 108 and 110,, utilizing the knob 136 of Figure 2,, the Long...

...Cap 162, The entire sequence of events as described for the implantation of the spinal **implant** I as already placed,, is then repeated such that both **spinal** **implants** come to lie side by side within the interspace, Though not necessary, circlage or other...Predistraction And Utilizing A Guarded Sleeve
System Is Disclosed
Because of the absence of the **spinal** cord and nerve roots, it is generally possible to visualize in one instance the entire width of the disc space from side to side throughout the cervical, thoracic, or lumbar **spine** , In the preferred embodiment of the anterior interbody fusion, **implants** are placed side by side from anterior to posterior parallel to the interspace and extending...

...the transverse
width of the disc space is insufficient to allow for the use of **two** **implants** , each of which would be large enough to protrude to the required depth into the adjacent **vertebrae** , then a singular and significantly larger **implant** may be placed centrally. With this in mind, and in light of the very detailed...

...in regard to the method of
posterior lumbar interbody fusion, a brief discussion of anterior **spinal** interbody fusion with dual **implant** installation will suffice, and the method for installation of a large, singular midline graft will become obvious.

The interspace to be fused is exposed anteriorly.

The soft tissues are **withdrawn** and protected to either side, and if necessary, above and below as well, It is...

...great bulk of
the nuclear disc portion. (Alternatively, the disc can be left to be **removed** via the drill later,) The surgeon then notes and marks a point midway from side to side anteriorly. He then **inserts** Long Distractor 100 centering it on a point midway between the point just noted and...Distractor 100 producing the ideal
interspace distraction having its barrel portion 106 corresponding to the **implant** to be installed has been **inserted** , then its exact duplicate is inserted anteriorly equidistant to the other side of the **spine** . As the barrel portion 106 of Long Distractor 100 is exactly of the same major diameter as the **spinal** **implant** I looking coaxially on end, the surgeon can then asses the anticipated side by side...

...As shown in Figures 7C and 7D,, a Dual Outer Sleeve 340 consisting of a **pair** of hollow tubes is then **introduced** over the side by side Long Distractors protruding anteriorly from the **spine** . The Dual Outer Sleeve 340 is comprised of two hollow tubular members identical in size **displaced** from each other ideally the sum of the difference between the minor and major diameters of

both **implants** combined, but not less than that difference for one implant, as it is possible to...

...slightly greater than two times the difference between the major and minor diameters of the **implant** (the sum of **both**) the distance may be considerably greater. Whereas in the preferred embodiment extending tubular portions 348...

...may be inclined or declined relative to each other such that they either converge or **diverge** at their proximal ends, Paired tubular structures 348, may be bridged in part or wholly...rigidly held via Foot Plate 344 and the prongs 342, Thus, it is possible to **remove** either one, or if desired, both of the Long Distractor rods utilizing Long Distractor puller...

...is then the surgeon's choice to work on one or both sides of the **spine** .

As per previous discussion, the surgeon may drill the interspace utilizing the Inner Sleeve 242...

...the Long Distractors in place as per the "Trephine Method", Tapping, if necessary, and the **insertion** of the **implants** then occurs through the protective Outer Sleeve 340, Once the **implants** have been fully **inserted** , the Outer SUBSTITUTE SHEET (RULE KM I Sleeve is **removed** . Having utilized the Drill method,, or "Trephine Method". with or without an Inner Sleeve to...

...implant I.

It is anticipated that the surgeon wishing to being inserted, may choose to **remove** the Outer Sleeve after the insertion of the first prosthesis to maintain stability, or prior...

...Preferred Embodiment For Method Of Anterior Interbody Fusion As previously described for the posterior lumbar **spine** , alternatively, one can employ the "Trephine Method" as has been described in detail.

As a...

...the preferred embodiment, it is nevertheless within the scope of this invention that one could **remove** the Outer Sleeve as there SUBSTITUTE SHEET (RULE 26) are no neural structures requiring protection, and **insert** the **implants** directly rather than through the Outer Sleeve, As yet a further alternative of this method...

...depth into the opposed vertebral bodies is such that it is not possible to place **two** such **implants** side by side, then only a single implant which may be of significantly increased diameter...

...drill or the "Trephine Method",
Referring to Figures 16-18, a cylindrical
embodiment of the **spinal** implant I of the present invention
is shown. In Figure 16 the implant I is shown...

...I is shown installed in the disc space D, between the
adjacent vertebrae,
The cylindrical **implant** I comprises a hollow
tubular member which in the preferred embodiment is made of
an...

...the present invention has been described in
association with the implant of a threaded spinal **implant** ,
it is recognized that other forms of **implants** may be used
with the present method, For example, dowels, made from
bone or artificial materials, knurled or irregularly shaped
cylinders or spheres, or any other shaped **implants** that can
be **introduced** through the outer sleeve may be used, Being
able to perform the procedure through the...

Claim
... between at least
some of said teeth.
5e The apparatus of claim I including a **removable** hollow
inner tubular sleeve.

6 The apparatus of claim 5 in which said inner sleeve...

...The apparatus of claim 1 in which said outer sleeve
includes means for restricting its **removal** from the
disc space after insertion.
8e The apparatus of claim 7 in which said means f or
restricting **removal** comprises ratchetings.
The apparatus of claim 1 in which said outer sleeve
has an increased...

...than the outside diameter of said increased diameter
portion of said outer sleeve,

11 A **spinal** distractor, said **spinal** distractor having a
f ront portion the width of a disc space between adjacent
vertebra...

...barrel from entering the disc space, said
second end terminating in a head.

12 The **spinal** distractor of claim 11 in which said second
end of said barrel has a reduced diameter portion.

13 The **spinal** distractor of claim 11 in which said barrel
is **removably** attached to said front portion.

14 The sr- inal distractor of claim 13 in which...

...for engaging a
corresponding threaded portion in the first end of said
barrel,

15 The **spinal** distractor of claim 14 in which said front

portion includes an engagement means for engaging a corresponding engaging means on the first end of said barrel.

16 The **spinal** distractor of claim 15 in which said barrel includes a central opening and a shaft...

...third threaded portion for engaging the second threaded portion of said front portion,

17 The **spinal** distractor of claim 16 in which said second S'JDcMTUTE SHEET 20) end of said shaf t includes a head having a reduced diameter portion.

18 The **spinal** distractor of claim 12 including a **removably** attachable knob having means for releasably engaging said head,

19 The **spinal** distractor of claim 18 in which said knob engages the reduced diameter portion of said...

...24 The apparatus of claim 20 in which said engagement means comprises projections.

25* A **spinal** distractor **removing** device for **removing** a distractor in a disc space, consisting of a shaft, a means f or attaching to a **spinal** distractor at one end and an increased diameter portion at the other end and a...

...comprises a slot f or engaging a reduced diameter portion of the head of a **spinal** distractor.

27o A drilling member for use in a **spinal** surgical ra i 11V z SUBSTITUTE SHEET (RL 26) procedure comprising a drill bit, said...

...28 in which said stop means is lockably adjustable.

30 Apparatus for use in performing **spinal** surgery comprising a hollow tubular member having drill teeth at one end and a cylindrical...

...stopping means is lockably adjustable.

33* A combined distractor and drill for use in performing **spinal** surgery comprising a hollow drill bit having teeth and a nipple extending from one end, said nipple distally formed to be a **spinal** distractor,

34 Apparatus for use in **spinal** surgery comprising a handle, a shaft, said shaft connected to said handle at one end...

...off centered to the central axis of said handle.

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35 An **implant** loading device for use in **spinal** surgery comprising a bone harvester having a first hollow tubular member having cutting teeth at...hollow tubular member.

36 The apparatus of claim 35 in which said bone harvester is **removably** connectable to a drilling attachment for engagement with a drill.

37 The apparatus of claim...

...harvester is approximately the diameter of said implant.

38 An implant removal/insertion device for **inserting** or removing an **implant** in the body of a patient, said implant having a generally cylindrical configuration, a thread on its outside perimeter and a central threaded portion; said **removal** /insertion device comprising a first tubular member having an outside diameter and thread corresponding to...

...the implant, whereby, said engaging means is fixed to said implant; said engaging means being **rotatable** in relationship to said first tubular member.

39 The device of claim 38 further including...

...in which said engaging means has handle means extending perpendicularly from said engaging means for **rotating** said engaging means.

42* A method for inserting a spinal implant between two adjacent **vertebrae** comprising **inserting** a hollow tubular member having engagement means for engaging two adjacent vertebrae into the vertebrae...

...member to drill a hole in the disc and a portion of the two adjacent **vertebrae** ; removing the drill; inserting an implant in the **vertebrae** through said tubular member; is and then **removing** said tubular member.

43 The method of claim 42 in which said implant is cylindrical.

44 The method of claim 42 in which said step for inserting an **implant** comprises **inserting** one or more partially cylindrical **implants** ,

45 The method of claim 42 in which said implant has a diameter corresponding to...

...RULP 28)

48 The method of claim 42 in which the tubular member has a **removable** hollow inner sleeve.

49 The method of claim 42 in which the hollow tubular member has means for limiting its **penetration** into the vertebrae,

50 The **method** of claim 49 in which said depth limiting means is lockably adjustable.

51 The method...a thread.

54 The method of claim 42 in which the tubular member has a **removable** hollow inner sleeve.

55 The method of claim 54 in which said hole is drilled through the hollow inner sleeve and said hollow inner sleeve is **removed** prior to tapping said hole,
56o The method of claim 53 in which said tubular member has a **removable** inner sleeve.

57 The method of claim 56 in which said hole is drilled through the hollow inner sleeve and said hollow inner sleeve is **removed** prior to tapping said hole,
58 . The method of claim 55 in which the inside...
...diameter of the implant,
60* A method for inserting a spinal implant between two adjacent **vertebra** comprising inserting a **spinal** distractor in the disc space on one or both sides of the **spinal** column to provide for proper spacing of the disc space between the vertebra,, inserting over the **spinal** distractor a hollow tubular member having engagement means for engaging two adjacent vertebrae into the vertebrae; removing the **spinal** distractor from the hollow tubular member; passing a drill through the tubular member to drill a hole in the disc and a portion of the two adjacent **vertebrae** ; removing the drill; inserting an implant in the **vertebrae** through the tubular member; and then **removing** said tubular member,

61 The method of claim 60 in which said implant is cylindrical.

62 The method of claim 60 in which said step of inserting an **implant** comprises **inserting** one or more partially cylindrical **implants** .

63 The method of claim 60 in which said implant has a diameter corresponding to...

...RULE 26)

66 The method of claim 60 in which the tubular member has a **removable** hollow inner sleeve.

67 The method of claim 60 in which said hollow tubular member...

...into the vertebrae.

68 The method of claim 67 in which said means for limiting **penetration** is lockably adjustable.

69 The **method** of claim 60 in which said implant is made of bone.

70 The method of in which the tubular member has a **removable** hollow inner sleeve.

73 The method of claim 72 in which said hole is drilled through the hollow inner sleeve and said hollow inner sleeve is **removed** prior to tapping said hole,

74 The method of claim 72 in which the inside...

...diameter of
the hollow inner sleeve is slightly greater than the root diameter of the **implant** .

76 The method of claim 60 in which one spinal distractor remains in place in the disc while a first **implant** is being **inserted** ,

77 The **method** of claim 76 in which said **spinal** distractor
SUBSTITUTE SHEET (RULE 26)
remaining in place includes a barrel portion that is separable...

...of the spinal implant in
the disc space.
78* A method for inserting a spinal **implant** between two adjacent vertebra comprising inserting a **spinal** distractor in the disc on one side of the **spinal** column to provide for proper spacing of the disc space between the vertebra,, inserting over the **spinal** distractor a hollow tubular member having engagement means for engaging two adjacent vertebrae into the vertebrae; passing a trephine through the tubular member and over the **spinal** distractor to drill a hole in the disc and a portion of the two adjacent vertebrae; removing the trephine; inserting an implant in the **vertebrae** through the tubular member; and **removing** said tubular member.

79 The method of claim 78 in which said implant is cylindrical,

80 The method of claim 78 in which said step of inserting an **implant** comprises **inserting** one or more partially cylindrical **implants** .

81 The method of claim 78 in which said implant has a corresponding diameter to...

...said trephine,
85 The method of claim 78 in which the tubular member has a **removable** hollow inner sleeve.

86 The method of claim 78 in which said hollow tubular member...

...cylindrical implant has a thread,

91 The method of claim 78 in which the one **spinal** distractor remains in place in the disc while the first **implant** is being **inserted** .

92 The **method** of claim 91 in which said **spinal** distractor remaining in place includes a barrel portion that is separable from the front portion of the **spinal** **implant** in the disc space.

93 The method of claim 78 further including the step of freeing and **removing** any remaining bone cut by the trephine

from within the trephine,

94 The method of claim 93 in which the remaining cut bone is **removed** from the trephine by an apparatus comprising a handle, a shaft, said shaft connected to...

...diameter of said coil and
off centered to the central axis of said coil whereby **rotation** of said corkscrew causes said cutting tip to radially cut a path substantially the diameter...

...96 wherein the cutting tip is self aligning.

98 An impaction device for use in **spinal** surgery comprising:
a **spinal** distractor **inserted** in the disc space between **two** vertebrae;
a hollow tubular outer sleeve having a toothed front end and a circumferentially enlarged...

...crown.
103* A method for securing a hollow tubular sleeve to two adjacent vertebrae comprising:
inserting a **spinal** distractor in the disc space on one side of the vertebrae, ...internal shoulder to said outer sleeve until said
crown is seated within said second recess;
removing said driver cap from said back end; and
removing said distractor with a distractor pulling means leaving said outer sleeve in place.
104, The method of claim 103 in which said outer sleeve includes penetration preventing means for preventing **penetration** of said teeth.
105, The **method** of claim 104 in which said penetration preventing means is lockably adjustable.
106, The method...

34/3,K/17 (Item 17 from file: 348)
DIALOG(R)File 348:EUROPEAN PATENTS

00647112
SPINAL **STABILIZATION SURGICAL TOOL SET**
WERKZEUGSATZ ZUR STABILISIERUNG DER WIRBELSAULE
ENSEMBLE D'INSTRUMENTS CHIRURGICAUX DE STABILISATION DE LA COLONNE VERTEBRALE

PATENT ASSIGNEE:
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PATENT (CC, No, Kind, Date): EP 683651 A1 951129 (Basic)
EP 683651 B1 990929
WO 9417759 940818
APPLICATION (CC, No, Date): EP 94907232 940112; WO 94US586 940112
PRIORITY (CC, No, Date): US 15863 930210
DESIGNATED STATES: AT; BE; CH; DE; DK; ES; FR; GB; GR; IE; IT; LI; LU; MC; NL; PT; SE
INTERNATIONAL PATENT CLASS: A61F-002/44; **A61B-017/16** ; A61F-002/46
NOTE:
No A-document published by EPO
LANGUAGE (Publication,Procedural,Application): English; English; English
FULLTEXT AVAILABILITY:

Available Text	Language	Update	Word Count
CLAIMS B	(English)	9939	557
CLAIMS B	(German)	9939	598
CLAIMS B	(French)	9939	713
SPEC B	(English)	9939	8195
Total word count - document A			0
Total word count - document B			10063
Total word count - documents A + B			10063

SPINAL **STABILIZATION SURGICAL TOOL SET**
PATENT ASSIGNEE:
Sulzer **Spine** -Tech Inc...
...INTERNATIONAL PATENT CLASS: **A61B-017/16**
LEGAL STATUS (Type, Pub Date, Kind, Text):
...Transfer of rights to new applicant:
Sulzer **Spine** -Tech Inc...

SPECIFICATION I. BACKGROUND OF THE INVENTION

1. Field of the Invention
This invention pertains to a **spinal** stabilization surgical kit. More particularly, this invention pertains to a kit according to the pre...

...the population. In many cases, the chronic back problems are attributed to relative movement between **vertebrae** in the **spine** .
Orthopaedic surgery includes procedures to stabilize vertebrae. Common stabilization techniques include fusing the **vertebrae** together.
Fusion techniques include **removing** disc material which **separates** the **vertebrae** and impacting bone into the disc area. The impacted bone

fuses with the bone material...

...post-operative recovery. To this end and to increase the probability of a successful fusion, **spinal implants** have been developed. An example of such a **spinal implant** is shown in commonly assigned and co-pending U.S. patent application serial number 07...

...May 15, 1991 (claiming priority to July 6, 1989). That patent application teaches a threaded **spinal implant** which includes a hollow cylinder into which bone chips or bone slurry may be placed...

...The bone material grows through the holes to fuse with the bone material of the **vertebrae** .

A threaded **spinal implant** is also shown in U.S. Patent No. 5,015,247, dated May 14, 1991.

Said document describes artificial **spinal implants** . When placed into the **intervertebral** space remaining after excision of a damage disc, the cylindrical **implants** stabilize adjacent **vertebrae** . The **implants** have a central opening, for **insertion** of a bone graft, and a plurality of macro sized openings through the side walls of the cylindrical implant. The implants provide structural support and induce bone ingrowth through the **implant** and into the wall of the **vertebra** to induce fusion from one vertebra in the joint to the other. In addition to teaching a threaded **spinal implant** , U.S. Patent No. 5,015,247 shows a method of implantation including certain tools...

...form a bore into which the implant is threaded.

A threaded fusion cage and a **method** of **inserting** such a cage is also shown in U.S. Patent No. 4,961,740 to...

...bore for the implant by drilling over a pilot rod. In addition to the above, **spinal implants** are shown in U.S. Patent No. 4,875,915 to Brantigan dated November 7...

...a bore formed between bone to be fused.

When performing back surgery (such as placing **implants** in a **spine**) it is desirable that the surgical procedure be performed as quickly and as accurately as...

...is an object of the present invention to provide a kit for placing at least **two implants** in a **spine** in a procedure which can be done quickly and accurately.

In addition to the foregoing, it is known to be desirable to place **two implants** between opposing **vertebrae** (although a single **implant** procedure may be advisable in some circumstances). In a **two implant** procedure, bores are formed on opposite sides of the **vertebrae** to receive each of the **implants** . I have found that in such a procedure, the forming of the bores can cause...

...to urge against end plates of said first and second vertebrae and urge first and **second** vertebrae apart upon said **insertion** of said tapered forward end to distract the annulus fibrosis.

III. BRIEF DESCRIPTION OF THE...

CLAIMS 1. A kit for implanting at least **two** **spinal** fusion **implants** (10) into a disc space of disc material (214) **separating** first and second **vertebrae** (210, 212), said disc space and first and second vertebrae divisible into first and second side **separated** by a sagittal plane, wherein said kit includes a hollow tubular guard to protect soft tissue and a means for forming an **implant** bore, characterized by comprising:

a **plurality** of incrementally sized distraction plugs (54) to be inserted into said disc space at a...

...to urge against end plates of said first and second vertebrae and urge first and **second** vertebrae apart upon said **insertion** of said tapered forward end 58 to distract the annulus fibrosis.

2. A kit according...

...an implant driver (164) having means on a distal end thereof for releasably engaging an **implant** and **turning** said **implant** upon **turning** of said driver, said driver sized to be slidably received within said drill tube (92...

...a first reamer (112) having means on a distal end thereof for boring into said **vertebrae** upon **turning** of said reamer and further having means on said distal end for releasably receiving a...

34/3,K/26 (Item 26 from file: 348)
DIALOG(R)File 348:EUROPEAN PATENTS

00972071
Instrumentation for implant insertion
Intrumentarium zum Einsetzen von Implantaten
Instrumentation pour poser un implant
PATENT ASSIGNEE:
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PATENT (CC, No, Kind, Date): EP 880938 A1 981202 (Basic)
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APPLICATION (CC, No, Date): EP 98109238 980520;
PRIORITY (CC, No, Date): US 48045 P 970530
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INTERNATIONAL PATENT CLASS: **A61B-017/02** ; A61F-002/46
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FULLTEXT AVAILABILITY:

Available Text	Language	Update	Word Count
CLAIMS A	(English)	199849	588
CLAIMS B	(English)	200350	380
CLAIMS B	(German)	200350	340
CLAIMS B	(French)	200350	403
SPEC A	(English)	199849	5062
SPEC B	(English)	200350	5041
Total word count - document A			5650
Total word count - document B			6164
Total word count - documents A + B			11814

INTERNATIONAL PATENT CLASS: **A61B-017/02** ...

...SPECIFICATION and, in particular, to a method and instrumentation for insertion of a pair of spinal **implants** to facilitate fusion of adjacent **vertebral** bodies.

2. Background of the Related Art
A large number of orthopedic **procedures** involve the **insertion** of either natural or prosthetic **implants** into bone or associated tissues. These procedures include, for example, ligament repair, joint repair or replacement, non-union fractures, facial reconstruction, **spinal** stabilization and spinal fusion. In a typical procedure, an insert, **dowel** or **screw** is **inserted** into a prepared bore formed in the bone or tissues to facilitate repair and healing...

...particularly configured with cavities and bores to facilitate bony ingrowth and enhance anchoring of the **implant** at the **insertion** site. See, for example, U.S. Patent Nos.: 4,328,593 to Sutter et al...

...015,247 to Michelson; and 5,489,307 to Kuslich et al. These types of

implants are particularly well suited for intervertebral **spinal** fusion procedures necessitated by injury, disease or some degenerative disorder of the **spinal** disc. Subsequently, there may be progressive degeneration leading to mechanical instability between adjacent vertebrae necessitating...

...Both anterior (transabdominal) and posterior surgical approaches are used for interbody fusions of the lumbar **spine** . Fusions in the cervical area of the **spine** are primarily performed using posterior and anterior approaches as well. Typically, an implant such as a plug, **dowel** , prosthesis or cage is **inserted** into a preformed cavity inside the interbody, interdiscal space. Since it is desirable in these...

...to bone" bridge, connective tissue and at least a portion of the distal tissue is **removed** . Preferably, relatively deep cuts are made in the adjacent bones in order to penetrate into...

...of a surgical fusion implant, particularly, in intervertebral spinal fusion, is the formation of the **implant** receiving cavity or bore within the adjacent **vertebrae** . More particularly, the drilled bore must be equally centered within the intervertebral space and preferably parallel to the vertebral end plates to ensure **removal** of equal portions of bone from the adjacent vertebrae throughout the length of the cut...

...subsequent appropriate seating of the implant relative to the vertebral bodies.

Surgical instruments for facilitating **spinal** fusion **implant** **insertion** are known. For example, U.S. Patent No. 5,484,437 to Michelson discloses a...

...space.

Although current instrumentation and methods associated therewith for enhancing the placement of spinal fusion **implants** have been generally effective for their intended purposes, there exists certain limitations with the design...

...is in optimal alignment for a tapping procedure (if required) and reception of the spinal **implant** . Rather, such **orientation** is dependent directly upon the skill of the surgeon. Moreover, the outer sleeve, which is...

...surface of the adjacent vertebrae, is subject to disorientation or dislodgment during insertion and/or **removal** of the drill and/or tapping instrument. Similarly, the use of guide rods increases the...

...to implant the fusion cage and is also subject to possible misalignment.

In many surgical **implant** techniques, two implants are inserted within the **intervertebral** space in side-by-side or lateral relation to fully support the adjacent vertebrae across...

...these techniques, a first lateral side of the intervertebral space is prepared, e.g., by **removing** excess disc material and drilling/tapping a bore to receive the implant followed by insertion of the implant. Thereafter, the second lateral side is prepared for **implant** **insertion** in the same manner. During the initial preparation of the first lateral side of the...

...S. Patent No. 5,489,307 to Kuslich discloses a surgical method for implanting two **spinal** **implants** into a disc space utilizing a distraction **spacer** which is inserted initially within one side of the

intervertebral space. The rigid distraction spacer is intended to act against the **vertebral** end plates of the adjacent vertebrae to urge the vertebrae apart while the second side of the intervertebral space is prepared, by drilling/tapping, to receive an **implant** . Once the **implant** is **inserted** , the distraction **spacer** is **removed** and the side left unoccupied by **removal** of the **spacer** is prepared to receive the **second implant** .

The present disclosure is directed to a method and associated instrumentation to facilitate the **introduction** of at least **two** fusion **implants** , which maintains the desired disc height across the span of the intervertebral space and thereby...

...between the first and second supporting surfaces sufficient to distract the opposed tissue portions upon **insertion** thereof. The first and **second** supporting surfaces of each retractor arm may be substantially planar. The retractor arms may be...

...member configured for insertion at least partially into an intervertebral space between adjacent opposed vertebrae, **inserting** the distal end of the **two** elongate members of the retractor to distract lateral sides of the intervertebral space and performing...

...of the elongate members to perform the surgical procedure. In a preferred embodiment, a fusion **implant** is **inserted** through the opening of the one elongate member and between the distracted vertebrae to effect...

...FIG. 3;

FIG. 5 is a perspective view of a surgical kit for performing a **spinal** fusion procedure illustrating, from bottom to top, the double retractor of FIG. 1, an **implant insertion** apparatus, a surgical tap instrument, a drill instrument and a T-shaped handle;

FIG. 6...

...view illustrating a portion of the vertebral column;

FIG. 7 is a side view illustrating **insertion** of the **double** retractor of FIG. 1 within an intervertebral space defined between adjacent vertebrae;

FIG. 8A is...

...10 is a view similar to the view of FIG. 8A illustrating insertion of the **implant insertion** instrument with mounted fusion **implant** within the retractor to mount the implant within the tapped bore;

FIG. 11 is a...

...11-11 of FIG. 10 further illustrating insertion of the implant insertion instrument within the **intervertebral** space defined between adjacent **vertebrae** ;

FIG. 12 is a cross-sectional view illustrating the insertion of two **implants** within the **intervertebral** space;

FIG. 13 is a perspective view of an alternate embodiment of the double surgical retractor of FIG. 1 having a spacing member interposed between the retractor sleeves to laterally **displace** the two retractor sleeves;

FIG. 14 is a top plan view of the double retractor...

...preferred embodiments of the method and instrumentation disclosed herein are discussed in terms of orthopedic **spinal** fusion procedures and instrumentation. It is also envisioned, however, that the disclosure is applicable to...

...not limited to ligament repair, joint repair or replacement, non-union fractures, facial reconstruction and **spinal** stabilization. In addition, it is believed that the present method and instrumentation finds application in...

...incision.

The following discussion will include a description of each instrument utilized in performing a **spinal** fusion method followed by a description of the preferred method for **spinal** fusion utilizing the instrumentation in accordance with the present disclosure.

In the discussion which follows...

...bony structures, e.g., adjacent vertebral bodies, to facilitate the insertion and application of a **pair** of **implants** . However, it is envisioned that **double** retractor 10 may also be utilized to distract other structures as well including joints, ligaments...

...polymeric material and formed by injection molded techniques. Retractor sleeves 12a, 12b may be two **separate** components connected to each other by conventional means including adhesives, welding or the like or...

...the height of the space between adjacent bony structures to be distracted. For example, in **spinal** fusion application, the height "h" of each arm 18 preferably ranges from about 0.28...

...proximal end.

Referring still to FIG. 5, the various instruments utilized in performing a double **spinal** fusion procedure with the retractor 10 of the present disclosure are illustrated. These instruments include surgical drill 50, tap instrument 100, implant **insertion** instrument 150, fusion **implant** 200 and T-shaped handle 250 which is used to actuate each of the instruments...

...to completely tap the internal thread within the bore without interruption of the tapping procedure.

Implant insertion instrument 150 is configured for mounting and inserting fusion **implant** 200 within the **intervertebral** space. **Insertion** instrument 150 includes elongated shaft 152 having hex-head mounting section 154 at its proximal...

...grooves 160 which engage corresponding structure of implant 200 (e.g., inner longitudinal rails) to **rotatably** fix the **implant** on the collar, i.e., to prevent **rotational** movement of the **implant** 200 on the collar. Other **insertion** instruments and arrangements are also envisioned.

Implant 200 is uniquely designed for use in spinal fusion procedures. This **implant** 200 is generally disclosed in U.S. Patent No. 5,026,373 to Ray, the

...SPECIFICATION implant.

The present disclosure is directed to a method and associated instrumentation to facilitate the **introduction** of at least **two** fusion **implants** , which maintains the desired disc height across the span of the intervertebral space and thereby...

...between the first and second supporting surfaces sufficient to distract the opposed tissue portions upon **insertion** thereof. The first and **second** supporting surfaces of each retractor arm may be substantially planar. The retractor arms may be...

...member configured for insertion at least partially into an intervertebral space between adjacent opposed vertebrae, **inserting** the distal end of the **two** elongate members of the retractor to distract lateral sides of the intervertebral space and performing...

...of the elongate members to perform the surgical procedure. In a preferred embodiment, a fusion **implant** is **inserted** through the opening of the one elongate member and between the distracted vertebrae to effect...

...FIG. 3;
FIG. 5 is a perspective view of a surgical kit for performing a **spinal** fusion procedure illustrating, from bottom to top, the double retractor of FIG. 1, an **implant insertion** apparatus, a surgical tap instrument, a drill instrument and a T-shaped handle;
FIG. 6...

...view illustrating a portion of the vertebral column;
FIG. 7 is a side view illustrating **insertion** of the **double** retractor of FIG. 1 within an intervertebral space defined between adjacent vertebrae;
FIG. 8A is...

...10 is a view similar to the view of FIG. 8A illustrating insertion of the **implant insertion** instrument with mounted fusion **implant** within the retractor to mount the implant within the tapped bore;
FIG. 11 is a...

...11-11 of FIG. 10 further illustrating insertion of the implant insertion instrument within the **intervertebral** space defined between adjacent **vertebrae** ;
FIG. 12 is a cross-sectional view illustrating the insertion of two **implants** within the **intervertebral** space;
FIG. 13 is a perspective view of an alternate embodiment of the double surgical retractor of FIG. 1 having a spacing member interposed between the retractor sleeves to laterally **displace** the two retractor sleeves;
FIG. 14 is a top plan view of the double retractor...

...S)
The preferred embodiments of the instrumentation disclosed herein are discussed in terms of orthopedic **spinal** fusion procedures and instrumentation. It is also envisioned, however, that the disclosure is applicable to...

...not limited to ligament repair, joint repair or replacement, non-union fractures, facial reconstruction and **spinal** stabilization. In addition, it is believed that the present method and instrumentation finds application in...

...incision.
The following discussion will include a description of each instrument utilized in performing a **spinal** fusion method followed by a description of a method for **spinal** fusion utilizing instrumentation that is accordance with the present disclosure.
In the discussion which follows...

...bony structures, e.g., adjacent vertebral bodies, to facilitate the insertion and application of a **pair** of **implants** . However, it is envisioned that **double** retractor 10 may also be utilized to distract other structures as well including joints, ligaments...

...polymeric material and formed by injection molded techniques. Retractor sleeves 12a, 12b may be two **separate** components connected to each other by conventional means including adhesives, welding or the like or...
...the height of the space between adjacent bony structures to be distracted. For example, in **spinal** fusion application, the height "h" of each arm 18 preferably ranges from about 7.1...

...proximal end.
Referring still to FIG. 5, the various instruments utilized in performing a double **spinal** fusion procedure with the retractor 10 of the present disclosure are illustrated. These instruments include surgical drill 50, tap instrument 100, implant **insertion** instrument 150, fusion **implant** 200 and T-shaped handle 250 which is used to actuate each of the instruments...

...to completely tap the internal thread within the bore without interruption of the tapping procedure.
Implant insertion instrument 150 is configured for mounting and inserting fusion **implant** 200 within the **intervertebral** space. **Insertion** instrument 150 includes elongated shaft 152 having hex-head mounting section 154 at its proximal...

...grooves 160 which engage corresponding structure of implant 200 (e.g., inner longitudinal rails) to **rotatably** fix the **implant** on the collar, i.e., to prevent **rotational** movement of the **implant** 200 on the collar. Other **insertion** instruments and arrangements are also envisioned.
Implant 200 is uniquely designed for use in spinal fusion procedures. This **implant** 200 is generally disclosed in U.S. Patent No. 5,026,373 to Ray, and...

...body 202 includes a single continuous thread (preferably V-shaped) having a plurality of raised **turns** with valleys defined between adjacent **turns** .
A plurality of perforations are disposed within the thread and extend through the outer surface...

...recess 254 which receives the corresponding structure of drill instrument 50, tap instrument 100 and **implant insertion** instrument 150.

Operation of the Instrumentation
The use of the instrumentation in conjunction with the insertion of a pair of fusion **implants** 200 into an **intervertebral** space defined between adjacent **vertebrae** will be described. The subsequent description will be particularly focused on an anterior procedure for **spinal** surgery although a posterior approach is envisioned as well.
With reference to FIG. 6, which...

...50 is advanced into the intervertebral space "i" adjacent the first lateral side "S1))" by **rotating** T-handle 250 such that drill bit 56 shears the soft tissue and cuts the...

...forming a bore which extends into the adjacent vertebrae "V1)), V2))". Drill 50 is then **removed** from retractor sleeve 12a. The drilling **procedure** is then repeated by **insertion** of drill instrument 50 within the second retractor sleeve 12b to form a bore within...

...surgical drill 50. With retractor sleeve 12a as a direct guide, T-handle

250 is **rotated** in the direction of the directional arrow of FIG. 9A while simultaneously applying sufficient downward...

...chips collect within conveyance channel 108 of tapping head 106, and are conveyed proximally during **rotational** movement of the tapping head 106 away from the tapping site. Tap instrument 100 is...

...the bone. When tap instrument 100 reaches the appropriate depth, the tap instrument 100 is **rotated** via T-handle 250 in an opposite direction to back the instrument out of the bore. The tapping **procedure** is then repeated by **insertion** of tap instrument 100 within the second retractor sleeve 12b to form a bore within...

...100 is not necessary.

With reference now to FIG. 10, attention is focused on the **insertion** of fusion **implant** 200. FIG. 10 shows a first fusion implant 10 already applied within the bore proximate the first lateral side "S1))" of the **intervertebral** space i. To apply the fusion **implant** , cage body 202 of the fusion **implant** 200 is mounted onto **insertion** instrument 150 by positioning the cage body 202 onto mounting collar 156 of the instrument ...

...of retractor 10 and the cage body 202 is positioned within the tapped bore by **rotating** insertion instrument 150 in the direction depicted in FIG. 10. Cage body 202 is advanced...

...completely seated with the bore as shown in FIG. 11. Insertion instrument 600 is then **removed** from retractor 100.

At this point in the procedure, bone growth inducing substances may be ...

...end cap may then be mounted to the cage body 202. Retractor 10 is then **removed** . It is also contemplated that the implant could be at least partially packed with bone growth inducing substances prior to insertion.

FIG. 12

34/3,K/141 (Item 141 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00529605 **Image available**

METHODS AND APPARATUS FOR SEPARATING AND STABILIZING ADJACENT VERTEBRAE
PROCEDES ET APPAREIL PERMETTANT DE SEPARER ET DE STABILISER DES VERTEBRES ADJACENTES

Patent Applicant/Assignee:
NUVASIVE INC,
Inventor(s):
MARINO James F,

Patent and Priority Information (Country, Number, Date):
Patent: WO 9960957 A1 19991202
Application: WO 99US11686 19990526 (PCT/WO US9911686)
Priority Application: US 9886945 19980527; US 98113651 19981223; US 99120663 19990219
Designated States: AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG UZ VN YU ZW GH GM KE LS MW SD SL SZ UG ZW AM AZ BY KG KZ MD RU TJ TM AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG
Publication Language: English
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Fulltext Availability:
Detailed Description
Claims

Detailed Description

... and 19b are positioned side-by-side between the adjacent vertebrae with the inserts being **positioned** at an angle C to one another in a laterally spaced-apart **orientation** , as shown. The advantage of positioning **inserts** 19a and 19b at an angle to one another is the increased stability between vertebrae...

...degrees, and most preferably be about 90 degrees. As can be seen in Fig. 10, **inserts** 19a and 19b are therefore each preferably posterolaterally percutaneously introduced at an angle D being...

...56 passing through the patient's sagittal plane Anterior-posterior axis 56 is perpendicular to **spinal** axis 58.

As can be seen therefore, only two cannulae 54a and 54b are required to enter through the patient's back when separating and stabilizing **vertebrae** 50 and 52 by implanting **inserts** 19a and 19b. As such, a very minimally invasive surgical technique is provided as compared to existing **insert systems** requiring open posterior **techniques** .

For reasons already set forth, should cannulae 54a and 54b preferably have non-symmetrical cross-sections, the potential for tissue damage is greatly reduced and the ability to position **inserts** 19a and 19b in the desired **orientation** within the **intervertebral** space is greatly enhanced. In this aspect of the method, prior disc distraction with dedicated...

...is not required.

In an aspect of this method, as also illustrated in Fig. 10, **two** posterolaterally **introduced** percutaneous cannulae 54a and 54b are used to introduce first and. **second inserts** , 19a and 19B, respectively, as set forth above; however, **insert** 19a is first **introduced** through cannula 54a concurrently with an instrument 39 being introduced through cannula 54b. Instrument 39...

...operated concurrently with the implantation of insert 19a into the patient's intervertebral space.

Subsequently, **insert** 19a is anchored into **position** by a positioning rod which is then detached from the **insert** .

Instrument 39 is then **removed** from cannula 54b and introduced into cannula 54a to perform the same function while **insert** 19b is **introduced** into the patient's **intervertebral** space through cannula 54b and anchored into position by a positioning rod which is also then **detached** .

Important advantages of this method, as distinguished from existing intervertebral systems, include the fact that there is no need in any of the present methods of **separating** and stabilizing adjacent **vertebrae** for drilling, chiseling or otherwise coring out large portions of the vertebrae to make way for the **insert** during the implantation **procedure** .
As is best seen in Fig. 16, an additional important advantage of using **inserts** 19a and 19b **positioned** at right angles to one another is that surfaces 32 and 34 are angled with...

...50 and 52 apart at a proper lordotic angle, preferably being about 10 degrees. Specifically, **inserts** 19a and 19b are preferably **positioned** inverted to one another such that sides 30 oppose one another and sides 28 are...

...in Fig. 15, the present invention also includes a kit 60, which can include intervertebral **insert** 20. For illustration purposes, **insert** 20 is shown in Fig.

15. It is to be understood that kit 60 can alternatively include any other intervertebral **insert** including, but not limited to, **inserts** 21 and 23 instead or in addition to **insert** 20. Kit 60 further includes instructions for use 62 which may be in the form...

...36a
with respect to one another may be constant from end 22a to 22b of **insert** 20a. However, as is shown in Figs. 24a, 24b, and 24c, the angle of surfaces 32a and 36a with respect to one another may instead vary along the length of **insert** 20a from end 22a to end 24a, also assisting in providing lordosis.

Similarly, with regard to the **insert** shown in Fig.

4B, it is also to be understood that the angle of surfaces 32 and 36 with respect to one another, may also vary along the length of **insert** 20 from end 22 to end 24, also assisting in providing lordosis.

Increasing numbers of **intervertebral** **inserts** will provide an increased surface area for support between the adjacent vertebrae. Accordingly, the present invention also encompasses inserting more than 2 **inserts** into the patient's **intervertebral** space, as follows. Figs. 25 to 31 show sequential steps in inserting a quartet of **inserts** 200, 210, 220 and 230, as follows. In Fig. 25, a first **insert** 200 is **inserted** into a patient's **intervertebral** space and **rotated** into position by rod 202 received through cannuia 204.

Subsequently, as shown in Fig. 26, rod 202 is **removed** and push rod 213 is inserted through cannula 214, moving **insert** 200 in direction D1. Subsequently, as shown in Fig. 27, a second **insert** 210 is **inserted** into a patient's **intervertebral** space and **rotated** into position by rod 212 received through cannula 214. Subsequently, as shown in Fig.

28, rod 212 is **removed** and push rod 203 is inserted through cannuia 204, moving inserter 210 in direction D2...

...Fig. 29, a third inserter 220 is inserted into a patient's intervertebral space and **rotated** into position by rod 202 received through cannula 204.

Subsequently, as shown in Fig. 30, rod 202 is **removed** and push rod 213 is inserted through cannula 214, moving **insert** 220 in direction Dl. Finally, as shown in Fig. 34, a fourth **insert** 230 is **positioned** in the patient's **intervertebral** space using the above described methods. An optional temporary distractor 250 may be positioned in...

...patient's intervertebral space during the above described procedure to increase the access for sliding **inserts** 200, 210, 220 and 230 into position.

The illustrations of Figs. 28 to 34 showing a quartet of inserts 200, 210, 220, and 230 **inserted** into the patient's intervertebral space is exemplary of the number of **inserts** which may be **inserted** into the **intervertebral** space.

As such, more than four **inserts** , (for example 6, 8f 10 or more), may instead be used. In addition, odd numbers of **inserts** may be used as well, such as when dealing with nonsymmetries in the patient's **intervertebral** space.

inserts 200, 210, 220, and 230 may comprise any of **inserts** 20, 21, 19 and 32 as described herein, however, it may be preferable to use **inserts** without fins so as to facilitate sliding movement of the **inserts** in respective Dl and D2 directions.

I 1. A method for separating and stabilizing adjacent vertebrae, the method comprising.

introducing a first insert between the vertebrae;
and
rotating the **insert** to engage cam surfaces thereon
against the **vertebrae** to move them apart.

2. The method as in claim 1, further comprising
anchoring the insert between the **vertebrae** .

3. The **method** as in claim 1, wherein the **insert**
is **inserted** percutaneously.

4. The **method** as in claim 3, wherein
percutaneous insertion of the **insert** comprises **introducing** a
cannula and introducing the **insert** therethrough.

I S. The **method** as in claim 3, wherein the cannula
has a non-symmetrical passage therethrough.

6. The...in claim 1, further comprising.
introducing a second insert between the vertebrae,
wherein the second **insert** is laterally spaced apart from the
first insert; and
rotating the second **insert** to support **separation**
of the adjacent **vertebrae** .

8. The method as in claim 7, further comprising
anchoring the first and second inserts between the
vertebrae .

9. The **method** as in claim 2 or 8, wherein
anchoring comprises embedding penetrating elements on the
insert into opposed surfaces of the adjacent **vertebrae** .

I 10. The method as in claim 9, wherein anchoring
comprises rotating the **insert** until the **penetrating** elements
are fully **embedded** .

11. The **method** as in claim 7, wherein the first
and second **insert** are oriented at an angle to one another.

12. The method as in claim 11...
...prior distraction of the adjacent
vertebrae.

14. The method as in claim 1, wherein the **insert**
is **inserted** posterolaterally.

I 15. The **method** as in claim 1, further comprising
measuring the torque required to rotate the implant.

16...

...positioning an insert between
adjacent vertebrae along a spinal axis, the method
comprising.

introducing an **insert** between adjacent **vertebrae** ,
the **insert** having a cross-section with a long axis and a
short axis, wherein the **insert** is **inserted** while oriented
with its short axis being generally aligned with the spinal

axis; and
rotating the insert such that cam surfaces of the **insert** separate the adjacent **vertebrae** .

17. The method of positioning an **insert** between adjacent **vertebrae** as in claim 16, wherein **rotating** the inserc comprises **rotating** the **insert** such that opposi-le flat surfaces disposed at opposite ends of the long axis buttress...

...insert between adjacent vertebrae as in claim 16, wherein introducing the insert comprises introducing the **insert** percutaneously.

19. The method of positioning an **insert** between adjacent **vertebrae** as in claim 18, wherein introducing the **insert** comprises **introducing** the **insert** through a generally oval-shaped or racetrack-shaped cannula.

20. The method of positioning an **insert** between adjacent **vertebrae** as in claim 19, further comprising introducing a coring device through the generally ovalshaped or racetrack-shaped cannula.

21. The method of positioning an **insert** between adjacent **vertebrae** as in claim 16, wherein rotating the **insert** comprises **rotating** an elongated member connected to the insert.

20. The **method** of positioning an **insert** between adjacent **vertebrae** as in claim 16, wherein the elongated member is received in a general oval-shaped or racetrackshaped cannula.

21. The method of positioning an **insert** between adjacent vertebrae as in claim 16, wherein the **insert** is inserted posterolaterally.

22. The method of **positioning** an **insert** between adjacent **vertebrae** as in claim 16, wherein the **insert** is **inserted** at an angle to an anterior-posterior axis extending through the adjacent vertebrae.

23. The method of **position** an **insert** between adjacent **vertebrae** as in claim 24, wherein the angle is in the range from 35 to 90 degrees.

24. The method of positioning an **insert** between adjacent **vertebrae** as in claim 17, further comprising embedding anchoring fins extending from the opposite flat surfaces into the adjacent vertebrae.

25. A method of positioning a first and a second **insert** between adjacent **vertebrae** along a **spinal** axis, comprising.

introducina the first **insert** between adjacent **vertebrae** , the first **insert** having a cross-section having a long axis and a short axis, wherein the first **insert** is **inserted** while oriented with is short axis being generally aligned with the spinal axis;
introducing the second insert between adjacent vertebrae, the second **insert** having a cross-section having a

long axis and a short axis, wherein the second **insert** is **inserted** while oriented with its short axis being generally aligned with the spinal axis; wherein the first **insert** and second **insert** are oriented at an angle to one another.

26. The method of positioning a first...

...second insert through the second cannula.

28. The method of positioning a first and a **second** **insert** between adjacent **vertebrae** , as in claim 29, -qbnoaqqaaaqq abessed TPOTa4@uIwAs-uOu P SPq E eTnuuPO Gq4 'UTGaGqM...a UT@;.-I@;IIMc 98911/66SfIlIDd 6Z L5609/66 OM

35. The method for percutaneously **introducing** an intervertebral **insert** as in Claim 36, wherein, the nonsymmetrical passage is oval-shaped or racetrack-shaped.

36. A method for percutaneously introducing an **intervertebral** **insert** between two adjacent **vertebrae** , comprising,
percutaneously **introducing** a first and a **second** cannula in posterolateral approaches through a patient's back, the first and **second** cannulae being **introduced** on opposite sides of an anterior-posterior axis through the patient;
introducing an **insert** through the first cannula into an **intervertebral** space between the two adjacent vertebrae; and
introducing an instrument through the **second** cannula into an intervertebral space between the two adjacent vertebrae.

37. The method for percutaneously **introducing** an intervertebral **insert** as in claim 38, wherein, the instrument is selected from the group consisting of a...

...shaver, osteophyte file, and bone graft introducer.

38. The method for percutaneously introducing an intervertebral **insert** as in claim 39, further comprising,
introducing a **second** **insert** through the first cannula into an **intervertebral** space between the **two** adjacent vertebrae; and
introducing the instrument through the first cannula into an intervertebral space between the two adjacent vertebrae.

. A kit comprising,
an **intervertebral** **insert** ; and
instructions for use setting forth the method of Claim
40 An **intervertebral** **insert** comprising a body having an anterior end, a posterior end, a rotational axis between the...

...generally parallel to the rotational axis and which are adapted to engage and separate opposed **vertebral** surfaces when the insert is placed between adjacent vertebrae and rotated.

41 The intervertebral **insert** as in claim 42,
wherein the insert tapers to a narrow posterior end.
142. The intervertebral insert as in claim 42,
wherein the **insert** has opposite flat **vertebral** support surfaces disposed at a lordotic angle to one another.

43 The **intervertebral insert** as in claim 42,
wherein the opposite flat surfaces have anchoring fins thereon.

44 The **intervertebral insert** as in claim 45,
wherein the anchoring fins are spaced apart in an anteriorposterior direction.

45 The intervertebral **insert** as in claim 42,
wherein the **insert** has a width and a height, the width being in the range of 1.5 to 3 times greater than the height.

46 The **intervertebral insert** as in claim 42,
further comprising, a fenestration passing through the insert.
. The **intervertebral insert** as in claim 48,'
wherein the fenestration passes through the **insert** in a direction generally parallel to the outwardly facing convex surfaces.

48 The **intervertebral insert** as in claim 48,
wherein the fenestration passes through the **insert** in a direction generally perpendicular to the outwardly facing convex surfaces.

49 The intervertebral insert as in claim 42,
wherein the **insert** is made of a bio-compatible material.
50 The **intervertebral insert** as in claim 42,
wherein the bio-compatible material is stainless steel, titanium, or carbon fiber composites.

51 The intervertebral insert as in claim 42,
wherein the **insert** is made of a bio-absorbable material.

52 The **intervertebral insert** as in claim 53
wherein the bio-absorbable material is selected from the group consisting...

...lactic acid, polyglycolic acid,
collagen, calcium phosphates, or bioabsorbable ceramics.

53 A system comprising,
an **insert** as in Claim 1, and
an insertion tool which is adapted to be axially attached to one end of the **insert** .

54 The **system** of Claim 55, wherein the one end is an anterior end of the **insert** .
55 The **system** of Claim 55, wherein the **insertion** tool is removably attached to the **insert** .

56 A **system** comprising,
an **insert** as in Claim 1, and

a cannula having a non-symmetrical passage therethrough.

57 An orthopedic **insert** , comprising,
an **insert** body adapted to be implanted within or adjacent to bone of a patient, wherein the **insert** has at least one surface which will be loaded by motion of the implant; and
a transducer within the **insert** body which is mechanically coupled to the at least one surface and which produces electrical...

...type and in an amount
sufficient to induce osteogenesis in the bone.

58 The orthopedic **insert** of Claim 59, wherein the transducer comprises a piezoelectric crystal.
59 The orthopedic **insert** of Claim 59, wherein
...first cannula
14 into the intervertebral space;
rotating the first insert, thereby positioning the first **insert** between adjacent **vertebrae** ;
advancing a first push rod through a second cannula to move the first **insert** away from the distal end of the first cannula;
advancing a second **inserter** through the **second** **inserter** into the intervertebral space;
rotating the second **inserter** ; and
advancing a **second** push rod through the first cannula to move the second **insert** in an direction away from a distal end of the second cannula.

64 The method...

...of claim 63, further comprising:
advancing a third insert through a first cannula into the **intervertebral** space;
rotating the third insert, thereby positioning the third **insert** between adjacent **vertebrae** ; and
advancing a first push rod through the second cannula to move the third **insert** away from the distal end of the first cannula.

66 The method of claim 63, further comprising:
advancing a fourth **insert** through the second cannula into the intervertebral space;
rotating the fourth insert, thereby positioning the fourth insert between adjacent **vertebrae** ;; and
advancing the **second** push rod through the first cannula to move the fourth **insert** away from the distal end of the second cannula.
I

34/3,K/143 (Item 143 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00529485 **Image available**
BONE BLOCKS AND METHODS FOR INSERTING BONE BLOCKS INTO INTERVERTEBRAL SPACES
BUTEES OSSEUSES ET INSERTION DE BUTEES OSSEUSES DANS LES ESPACES INTERVERTEBRAUX
Patent Applicant/Assignee:
NUVASIVE INC,
Inventor(s):
MCKINLEY James K,
MARINO MD James F,
STONE Corbett W,
Patent and Priority Information (Country, Number, Date):
Patent: WO 9960837 A2 19991202
Application: WO 99US11597 19990526 (PCT/WO US9911597)
Priority Application: US 9886945 19980527; US 98113651 19981223; US 99120663 19990219
Designated States: AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG UZ VN YU ZW GH GM KE LS MW SD SL SZ UG ZW AM AZ BY KG KZ MD RU TJ TM AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG
Publication Language: English
Fulltext Word Count: 7040

Fulltext Availability:
Detailed Description
Claims

Detailed Description
... from the inserter, reducing or eliminating the requirement of a push rod separating the bone **block** from the **inserter** .

The present bone **blocks** can be used singly, in pairs, or in quartets. When used in pairs or quartets, the bone blocks can be angled with respect to one another such that increased **vertebral** stability is achieved. Similarly, more than four bone **blocks** can be uses, and the present invention therefore also encompasses using 6, 8, 10 or more bone **blocks** to provide **intervertebral** stability.

In a first preferred aspect of the inventionf the inserter is received through a...

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00481129 **Image available**
METHOD **AND INSTRUMENTATION FOR** IMPLANT INSERTION
PROCEDE ET INSTRUMENT D' INSERTION **D'UN** IMPLANT
Patent Applicant/Assignee:
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METHOD **AND INSTRUMENTATION FOR** IMPLANT INSERTION
PROCEDE ET INSTRUMENT D' INSERTION **D'UN** IMPLANT
Main International Patent Class: **A61B-017/02**
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Detailed Description
Claims

English Abstract
A laparoscopic surgical retractor (100) for use during a laparoscopic **spinal** procedure includes an elongated sleeve member (102) having proximal and distal end portions, defining a...

...at least partially into an intervertebral space between adjacent opposed vertebrae to distract the adjacent **vertebrae** . A **method** for **inserting** a fusion **implant** (700) with the use of the retractor is also disclosed.

Detailed Description
METHOD AND TNSTRUMENTATTON FOR **IMPLANT** **INSERTION**
BACKGROUND
Technical Field
The present disclosure generally relates to a **method** and associated instrumentation for implant insertion and, in particular, to a method and instrumentation f9r insertion of **spinal** **implants** to facilitate fusion of adjacent **vertebral** bodies.
BackLyround of the Related Art
A large number of orthopedic **procedures** involve the **insertion** of either
natural or prosthetic implants into bone or associated tissues. These procedures include, for example, ligament repair, joint repair or replacement, non-union fractures, facial 1 5 reconstruction, **spinal** stabilization and **spinal** fusion. In a typical **procedure** , an **insert** , **dowel** or **screw** is **inserted** into a prepared bore formed in the bone or tissues to facilitate repair and healing...

...particularly configured with cavities and bores to facilitate bony ingrowth and enhance anchoring of the **implant** at the **insertion** site. See, for example, U.S. Patent Nos.: 4,328,593 to Sutter et al...

...015,247 to Michaelson; and 5,489,307 to Kuslich et al. These types of **implants** are particularly well suited for **intervertebral** **spinal** fusion procedures necessitated by injury, disease or some degenerative disorder of the **spinal** disc. Subsequently, there may be progressive degeneration leading to mechanical instability between adjacent vertebrae necessitating...

...Both anterior (transabdominal) and posterior surgical approaches are used for interbody fusions of the lumbar **spine** . Fusions in the cervical area of the **spine** are performed using an anterior or posterior approach as well. Typically, an implant such as a plug, **dowel** , prosthesis or cage is **inserted** into a preformed cavity inside the interbody, 0 interdiscal space. Since it is desirable in...

...to bone" bridge, connective tissue and at least a portion of the distal tissue is **removed** . Preferably, relatively deep cuts are made in the adjacent bones in order to penetrate into...

...facilitate bone growth across the implant.

One of the more critical tasks performed in the **insertion** of a surgical fusion 5 **implant** , particularly, in **intervertebral** **spinal** fusion, is the formation of the **implant** receiving cavity or bore within the adjacent **vertebrae** . More particularly, the drilled bore must be equally centered wid-iin the intervertebral space and preferably parallel to the **vertebral** end plates to ensure **removal** of equal portions of bone from the adjacent vertebrae throughout the length of the cut and subsequent appropriate seating of the **implant** relative to the **vertebral** 0 bodies.
Surgical instruments for facilitating **spinal** fusion **implant** **insertion** are known. For example, U.S. Patent No. 5,484,437 to Michelson discloses a...

...the intervertebral space.

Although current instrumentation and methods associated therewith for enhancing the placement of **spinal** fusion **implants** have been generally effective for their intended purposes, there exists certain limitations with the design...

...sleeve is in optimal alignment for a tapping procedure (if required) and reception of the **spinal** **implant** . 0 Rather, such **orientation** is dependent directly upon the skill of the surgeon. Moreover, the outer sleeve, which is...

...surface of the adjacent vertebrae, is subject to disorientation or dislodgment during insertion and/or **removal** of the drill and/or tapping instrument. Similarly, the use of guide rods increases the...

...379, filed March 14, 1996
discloses a novel method and associated instrumentation to facilitate the **introduction** of a fusion **implant** . 7be instrumentation disclosed in the '379 application ensures optimal alignment of the drilled bore for...

...instrumentation includes a surgical retractor and a drill. The retractor is configured for distracting adjacent **vertebral** bodies to facilitate the **insertion** and application of an **implant** , for providing a cannula for **insertion** of auxiliary instruments, e.g., the drill, and for ensuring proper alignment of the instrumentation and accurate **insertion** of the **implant** . 'Me instrumentation and method disclosed in the '379

application is 5 well suited for implanting...recovery time.

Thus, it would be advantageous to provide surgical instrumentation to facilitate minimally invasive **spinal** fusion procedures and particularly to facilitate minimally invasive placement of **spinal** fusion **implants** .

SUMMARY

Accordingly, the present disclosure is directed to further improvements and adaptations to the instrumentation and method disclosed in the '379 application to facilitate a I 0 laparoscopic approach to **spinal** fusion. Generally, the present disclosure is directed to a laparoscopic surgical retractor for use during a laparoscopic **spinal** procedure, including an elongated sleeve member having proximal and distal end portions and defining a...

...first and second supporting surfaces sufficient to 2 0 distract the opposed tissue portions upon **insertion** thereof. The first and **second** supporting surfaces of each retractor arm are preferably substantially planar.

The valve assembly may be...being correspondingly dimensioned to receive the rail, to thereby prevent relative rotational movement of the **insertion** tool and the fusion **implant** .

The **insertion** tool includes a drive member extending within a bore of the elongated member and reciprocally longitudinally movable between first and **second** 1 5 **positions** , and engaging structure disposed within the mounting portion. The engaging structure is movable between a disengaged **position** to disengage from the fusion **implant** corresponding to the first **position** of the drive member and an engaged **position** in engagement with the fusion **implant** corresponding to the **second position** of the drive member. The engaging structure includes an engaging ball at least partially disposed performing a surgical **spinal** procedure is also disclosed. The
method includes the steps of:
2 5 providing a laparoscopic...

...drawings wherein.

FIG. 1 is a perspective view of the surgical lit for performing a **spinal** fusion procedure through a laparoscopic approach illustrating, from bottom to top, a surgical retractor with mounted valve assembly and converter, an **implant** **insertion** apparatus, a 5 surgical tapping instrument, a drilling instrument, an impactor instrument and a T...

...retractor for
mounting the retractor housing;
0 FIG. 4 is a perspective view with parts **separated** of the retractor housing and
the valve assembly;
FIG. 4A is a perspective view with parts **separated** of the converter to be used
with the valve assembly;
FIG. 5 is an isolated...

...the lines 9-9 of FIG. 8;
FIG. 10 is a perspective view with parts **separated** of the impactor instrument; FIG. 1 1 is a perspective view of the distal end...

...valve assembly and mounted surgical impactor,

FIG. 15 is an enlarged perspective view of the **implant insertion** instrument; 1 5 FIG. 16 is an enlarged perspective view of the distal end of the **implant**
insertion instrument;
FIG. 17 is a perspective view with parts **separated** of the **implant insertion**
instrument;
FIG. 18 is a side cross-scctional view of the **implant insertion** instrument 2 0 with the fusion **implant** mounted thereto illustrating the engaged **position** of the insertion
instrument;
FIG. 19 is a view similar to the view of FIG. 18 illustrating the insertion instrument in a release **position** pemiitting release of the fusion **implant** ;
FIG. 20 is a cross-sectional view taken along the lines 20-20 of FIG. 18 2 5 illustrating corresponding mounting structure of the **insertion** instrument and the fusion
implant ;
FIG. 20A is a perspective view with a portion cut-away of the fusion implant...

...drill instrument; FIG. 24 is a view similar to the view of FIG. 23 illustrating **insertion** of the **implant insertion** instrument with mounted fusion **implant** within the retractor to mount the implant within the tapped bore;
FIG. 25 is a cross-sectional view illustrating the **insertion** of **two implants**
within the **intervertebral** space;
FIG. 26 is a perspective view of an alternative surgical retructor illustruting an
adaptor...

...preferred embodiments of the method and instrumentation disclosed herein are discussed in terms of orthopedic **spinal** fusion procedures and instrumentation. It is also envisioned, however, that the disclosure is applicable to...

...to ligament repair, joint repair or replacement, non-union 2 5 fractures, facial reconstruction and **spinal** stabilization. The present method and instrumentation finds application in minimally invasive procedures including endoscopic and...
...incision.

The following discussion will include a description of each instrument utilized in performing a **spinal** fusion method utilizing a laparoscopic anterior approach followed by a description of the preferrrd method for **spinal** fusion with the instrumentation in accordance with the present disclosure.

In the discussion which follows...to FIG. 1, there is illustrated in perspective view the surgical kit for performing a **spinal** fusion procedure through a laparoscopic approach in accordance I 0 with the principles of the...

...used with the valve assembly 200, impactor instrument 300, drill instrument 400, tap instrument 500, **implant insertion** instrument 600, fusion **implant** 700 mountable to the **insertion** instrument 600 and T-shaped handle 800.

Surgical Retractor
With reference to FIGS. 2...
...contents of which are incorporated herein by reference. Retractor 100 is configured for distracting adjacent **vertebral** bodies to facilitate the **insertion** and application of an **implant** , for providing a cannula for **insertion** of the instrument, and for ensuring proper alignment of the instrumentation and accurate **insertion** of the **implant** . Retractor 100 includes sleeve 102 with a mounting portion 104 disposed at the proximal end...

...the height of the space between adjacent bony structures to be distracted. For example, in **spinal** **implant** application, the height "h" of each arm may range from about 0.28 inches to...

...to the sleeve 102. In an alternate embodiment, instead of the notch/rib arrangement, a **screw** threaded engagement is utilized to atta h retractor housing 118 to sleeve 102.

With reference...portion 124 of seal 122 to provide support for the seal during -12 introduction and **withdrawal** of an elongated instrument. Stabilizing plate 132 includes two diametrically opposed extensions 134 which are...

...through the sleeve 102 and into the 0 body cavity. Insufflation gases can continually be **introduced** during the **procedure** to maintain the inflated condition of the peritoneal cavity.

Valve Assembly
Referring now to FIGS...is received within peripheral groove 232 of seal housing 208 and the entire assembly is **rotated** causing engagement of the radially inwardly projecting rib portions 234 adjacent the groove 232 with...

...to housing 118 can be readily determined by one skilled in the art such as **screw** threads, adhesives, bayonet locking and the like.

Another valve assembly suitable for use with retractor...

...an integral unit. As another alternative, the valve assembly 200 can be packaged as a **separate** unit and attached to the retractor 100 by the user.

Conve=
Referring to FIGS. 4...diameter instruments inserted therethrough. The different sized converters 250 may be readily exchanged by simple **withdrawal** and insertion within valve assembly 200. Similar commercially available converters (i.e. reducer sleeves) are...

...two components. Impactor head 326 defines a rounded end 332 which is advantageously dimensioned to **remove** tissue from the operative site. The crosssectional dimension of impactor head 326 is preferably greater ...used to completely tap the internal diread within the bore without interruption of the tapping **procedure** .

Insertion Instrumol
Referring now to FIGS. 15-18, **implant** **insertion** instrument 600 will be
discussed in detail. **Implant** **insertion** instrument 600 includes outer elongated sleeve 602 having proximal portion 604 and distal portion 606 ...channel 614 terminating in diametrically opposed radial openings 614a.

A deployment mechanism is incorporated within **implant insertion** instrument 2 0 600 for deploying fusion implant 700. The deployment mechanism includes manually actuated...

...Cam member 628 is movable through respective movement of the deployment mechanism between a release **position** to enable disengagement of the **implant** 700 from **insertion** instrument 600 and an engaged **position** to retain the **implant** 700 on implant mounting collar 608.

FIGS. 18-19 depict the deployment mechanism of **implant insertion** instrument 600 in the engaged and disengaged positions respectively. In the engaged position, manually actuated...

...engaged position by coil spring 634 which engages the proximal end of drive collar 622.

Implant insertion instrument 600 includes proximal hex head 636 for coupling to T-handle 800.

Fusion Implant.
Refer-ring again to FIG. 1, implant 700 will be described. **Implant** 700 is uniquely designed for use in **spinal** fusion procedures. This **implant** 700 is generally disclosed in U.S. Patent No. 5,026,373 to Ray, the... body 702 includes a single continuous thread (preferably V-shaped) having a plurality of raised **turns** with valleys defined between adjacent **turns** .

A plurality of perforations are disposed within the thread and extend through the outer surface...
...of mounting collar 608 when the implant 700 is mounted onto the collar 608, thus, **rotatably** fixing the **implant** 700 relative to **insertion** instrument 600. Arcuate inner recesses 706 of implant 700 receive portions of mounting balls 632...

...the deployment mechanism is in the engaged position of FIG. 18, thus, positively securing the **implant** 700 on the **insertion** instrument 600.
0
T,Handle
T-shaped handle 800 includes mounting portion 802 defining hexagonalshaped recess 804 which receives the corresponding structure of drill instrument 400, tap instrument 500 and **implant insertion** instrument 600.

5
Operation of Surgical Instrumentaflon
The use of the instrumentation in conjunction with the **insertion** of fusion **implant** 700 into an **intervertebral** space defined between adjacent **vertebrae** will be described. The subsequent description will be particularly focused on a laparoscopic anterior procedure...surface 138 of retractor sleeve 102. During insertion, impactor head 326 of impactor instrument 300 **removes** tissue from the operative site and also prevents entry of body fluids within the interior...

...retractor 100 in their appropriate position within the intervertebral space "i", impactor instrument 300 is **removed** from retractor 100 and valve assembly 200. During **removal** , valve 122 of retractor housing 118 assumes its closed position preventing egress of insufflation gases...

...the posterior surface of the vertebral bodies, "vl v2". DriU 400 is

advanced into the **intervertebral** space 'T' by **rotating** T-handle 800 such that drill bit 406 shears the soft tissue and cuts the...

...ning a bore which extends into the adjacent vertebrae "vl v2"- Drill 400 is then **removed** from retractor 100.

Referring now to FIG. 23, tap instrument 500 is selected and attached 800 is **rotated** in the direction of the directional arrow of FIG. 23 while simultaneously applying sufficient downward...

...the bone. When tap instrument 500 reaches the appropriate depth, the tap instrument 500 is **rotated** via T-handle in an opposite direction to back the instrument out of the bone...
...500 is not necessary.

With reference now to FIG. 24, attention is focused on the **insertion** of fusion **implant** 700. Cage body 702 is mounted onto insertion instrument 400 by positioning the cage body...

...the instrument to permit mounting ball 632 to engage one of the apertures of the **implant** 700. Initially, **insertion** instrumnt 600 is in the position of FIG. 18 such that mounting balls 632 are...

...into retractor 100 and the cage body 702 is positioned within the tapped bore by **rotating** insertion instrument 600 in the direction depicted in FIG. 8. Cage body 702 is advanced...

...balls 1 5 632 to move out of engagement with implant 700. Upon release of **implant** 700, **insertion** instrument 600 is **removed** from retractor 100.

At this point in the procedure, bone growth inducing substances may be...

...2 0 may then be mounted to the cage body 702. Retractor 100 is then **removed** . Alternatively, cage body 702 can be pre-packed with bone growth inducing substances prior to **insertion** .

FIG. 25 illustrates **two** lateral fusion **implants** 700 **inserted** within the
intervertebral space. The **second** **implant** 700 may be **inserted** in the same manner is discussed hereinabove.

Thus, the instrumentation and surgical procedure described herein provide a minimally invasive approach to the **insertion** of **spinal** **implants** for **spinal** fusion. It is envisioned that the approach will result in less trauma to the patient...precluding the need for impactor instrument 300. Once appropriately positioned, impactor head 140 may be **removed** and valve housing 11 8 may be mounted to proximal end 104 of retractor 100...

...example, several of the instruments described 1 5 herein e.g., the impactor instrument and **implant** **insertion** instrument, can be used in open procedures, as well as the aforedescribed minimally invasive procedures...

Claim

1. A laparoscopic surgical retractor assembly for use during a laparoscopic **spinal** procedure, which comprises:
an elongated sleeve member having proximal and distal end portions and defining...distal end, and a mounting portion disposed at the distal

end thereof-, and
a fusion **implant** releasably mounted to the **insertion** tool, the fusion **implant** including a cage body defining a longitudinal bore, the cage body positionable about the
5...

...being correspondingly dimensioned to receive the rail, to thereby prevent relative rotational movement of the **insertion** tool and the fusion **implant** .

15 An apparatus according to claim 14 wherein the cage body includes the rail extending...

...a bore of the elongated member, the drive member reciprocally longitudinally movable between first and **second positions** ; and engaging structure disposed within the mounting portion, the engaging structure movable between a disengaged **position** to disengage from the fusion **implant** corresponding to the first **position** of the drive member and an engaged **position** in engagement with the fusion **implant** corresponding to the **second position** of the drive member.

18 An apparatus according to claim 17 wherein the engaging structure...22 An apparatus according to claim 17 wherein the drive member is biased to the **second position** by a spring member.

23 A method for performing a surgical **spinal** procedure, comprising the steps of:
providing a laparoscopic surgical retractor including an elongated member having...

...of the surgical retractor and the impactor instrument drives the surgical retractor within the adjacent **vertebrae** ; and **removing** the impactor instrument from the surgical retractor.
1 5 26. 'Me method according to claim 23 wherein the step of performing includes inserting an **insertion** instrument having a fusion **implant** mounted to a distal end portion thereof within the opening of the surgical retractor and mounting the **implant** with the **insertion** instrument within the adjacent **vertebrae** . 2 0 27. The method according to claim 26 further including the steps of
introducing...

...actuating the drill instrument such that the distal drill head cuts a bore
in the **vertebral** bodies;
2 5 **removing** the drill instrument from the surgical retractor.
. Ile method according to claim 27 further including...

34/3,K/152 (Item 152 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00478544 **Image available**
APPARATUS AND METHOD FOR SPINAL **STABILIZATION**
APPAREIL ET PROCEDE DE STABILISATION SPINALE
Patent Applicant/Assignee:
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Inventor(s):
YONEMURA Kenneth S,
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Patent and Priority Information (Country, Number, Date):
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Priority Application: US 97921001 19970829
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APPARATUS AND METHOD FOR SPINAL **STABILIZATION**
APPAREIL ET PROCEDE DE STABILISATION SPINALE
Patent Applicant/Assignee:
SULZER **SPINE** -TECH INC...
Main International Patent Class: **A61B-017/17**
Fulltext Availability:
Detailed Description
Claims

English Abstract
A surgical method and apparatus for implanting a **spinal** fusion **implant** includes a rigid centering guide having a distal end sized to be inserted into the...

Detailed Description
APPARATUS AND METHOD FOR **SPINAL** STABILIZATION
1. BACKGROUND OF THE INVENTION
I Field of the Invention
This invention pertains to **spinal** stabilization surgical procedures and apparatus for performing such procedures. More particularly, this invention pertains to an apparatus and method for implanting a fusion **spinal** **implant** between two **vertebrae** .

2. Description of the Prior Art
Chronic back problems cause pain and disability for a...

...of the population. In many cases, chronic back problems are attributed to relative movement between **vertebrae** in the **spine** .

Orthopedic surgery includes procedures to stabilize **vertebrae** . Common stabilization techniques include fusing the **vertebrae** together.

Recently, **spinal** **implants** have been developed to facilitate successful ftision of **vertebrae** . In such procedures, a bore is formed between opposing **vertebrae** to be fused. An **implant** , commonly containing bone growth-inducing material such as harvested bone chips, is

placed within the...

...cuts equally into both vertebrae.

Also, from time to time, it is desirable to place **two implants** within the same disc space. In such procedures, it is desirable that the vertebrae be...

...during the implanting procedure. In the prior art, numerous methods have been disclosed for performing **spinal** stabilization procedures.

A **spinal implant** and stabilization procedure is taught in U.S. Patent Nos.

5,015,247 and 5...

...Michaelson, dated May 14, 1991 and January 16, 1996, respectively. That patent teaches a threaded **spinal implant** as well as a method of implantation including certain tools to form a bore into...

...where the conical implants have a conical angle approximating a desirable lordosis between the opposing **vertebrae** .

In surgical procedures involving **implants** , it is desirable that the surgical procedure be performed accurately to ensure central **positioning** of the **implant** within the disc space between the opposing **vertebrae** . U.S. Patent No. 5,489,307 to Kuslich, et al., dated February 6, 1996...

...a plurality of instruments and a surgical method for preparing a bore for receiving an **implant** . That **procedure** results in accurately **positioning** an **implant** centrally between the opposing **vertebrae** while avoiding certain disadvantages with other prior art techniques as discussed more fully in ...is an object of the present invention to provide an apparatus and method for performing **spinal** stabilization using a reduced number of instruments in order to simplify the procedure without sacrificing...

...preferred embodiment of the present invention, an apparatus and method are disclosed for implanting a **spinal** fusion **implant** into a disc space **separating** a first **vertebra** and a **second** vertebra. The **method** comprises **inserting** a distal end of a rigid centering guide into the disc space. The guide extends...
...present invention;
FIG. 2 is a view of the implant of FIG. I with the **implant rotated** 90' about
its axis;
FIG. 3 is a view taken along line 3-3 of...sleeve of FIG. 34;
FIG. 36 is a schematic posterior to anterior view of two **vertebrae separated** by a disc space and showing a dura extending centrally along a mid line between...

...7 inserted into the disc space between the vertebrae prior to the centering guide being **rotated** to a distraction position;
FIG. 39 is the view of FIG. 38 with the centering guide **rotated** to a distraction position;
1 0 FIG. 40 is a plan view of a disc...

...44 following formation of a tapped thread in the bore of FIG. 44 and showing **removal** of the tapping tool through the drill tube; FIG. 46 is the view of FIG. 45 showing an **implant inserted** into the threaded

bore of FIG. 45 and showing **removal** of the **implant** driving tool through the drill
tube;
FIG. 47 is a posterior-to-anterior view showing a dura retracted to a right side over an **inserted** **implant** and with the centering guide reversed and with a drill tube positioned against the centering...

...drill tube shown in
section;
FIG. 49 is an anterior-to-posterior view of two **vertebrae** **separated** by a disc space and showing a non-lordotic, anterior approach centering guide of the...

...guided by the centering guide;
FIG. 50 is the view of FIG. 49 showing an **implant** **inserted** into a formed
bore on a left side of the vertebrae and with the drill...

...54 of FIG. 53;
FIG. 55 is the view of FIG. 53 with drill tube **rotated** 90' about its longitudinal axis; and
FIG. 56 is a view taken along line 56-56 of FIG. 53.

5 IV. DESCRIPTION OF THE PREFERRED EMBODIMENT
A. **IMPLANT**
Referring now to the **several** drawing figures in which identical elements are numbered identically throughout, a description of the preferred...12. The cylinder includes a forward interior chamber 16 and a rear interior chamber 17 **separated** by a reinforcing rib 19. A bond slurry or bone chips may be compacted into...

...a distal end of a tool (as will be more fully described) to place the **implant** within a bore formed between opposing **vertebrae** . End caps (not shown) may be used with the **implant** . Such end caps are shown in U.S. Patent No. 5,489,307.

In a...

...of a kit necessary to perform the surgery as described in this application will be **separately** described. The use of the tools will become apparent with the description of the method...

...vary from patient-to-patient (and since such sizes vary along the length of the **spine** of any give patient), **several** sizes of **implants** 10 are anticipated. Presently, implants 10 having minor outside diameters (Dm) of 3 mm, 5...34 mm, 38 mm, 42 mm and 44 mm, respectively, are anticipated to accommodate various **spine** locations and sizes. The major outside diameters (D,,) of the **implants** 10 are 2.5 mm larger than the minor outside diameters Dm.

Several of the...without a drill tube and by using a drill, tap or other implement to facilitate **insertion** of an **implant** where the implement has a curved geometry to match the radius of curvature of the...168 sized to be received within slot 24 of the implant 10 to urge the **implant** 10 to **rotate** as the **implant** driver 164 is **rotated** . The **implant** driver 164 includes a stepped enlarged portion 170 including a first diameter portion 172, a...

...body 173 into groove 180a permits collet 171 to slide on shaft 166 but not **rotate** . Four prongs 177 extend axially from body 173 toward hub

168.

In use, shaft 166...use in a
posterior approach. In a posterior approach, a surgeon seeks access to the **spine** through the back of the patient. Another alternative approach is the lateral approach, where the...

...space.

An.alternative approach is an anterior approach where the surgeon seeks access to the **spine** through the abdomen of a patient. The approaches can be done through open surgery or...

...in either a prone or kneeling-sitting position. At the discretion of the surgeon, the **spine** is 1 5 flexed slightly. Anesthesia is administered.

Exposure of the intervertebral disc is obtained through any suitable technique well-known in the art. The facet of the **vertebrae** is **removed** in as limited amount as possible to permit **insertion** of the instruments and the **implants** . Preferably, bone dissected from the lamina, facets and **spinous** process are preserved for later use as bone graft.

FIG. 36 shows two **vertebrae** 200,200' **separated** by a disc space 202. For
ease of illustration, disc material is not shown in...

...the vertebrae 200,200' and is centrally positioned along a medial line, M, between the **vertebrae** 200,200'. The line M **separates** the disc space 202 and **vertebrae** 200,200' into a left side L and right side R corresponding to the patient1002 is **rotated** 90' to the position shown in FIG. 39 such that the side edges 1082 of...

...is selected to distract the annulus I 0 fibrosus without causing damage to the surrounding **vertebral** bone, annular fibers or **spinal** nerves. Accordingly, it is recommended that a surgeon initially **insert** a relatively narrow distal end centering guide (eg., 6 millimeters) followed by successively larger guides...

...shown in FIGS. 42
With the drill tube 92 in place, the preparation of the **implant** bore 206 is completed by **inserting** the reamer 126 into the drill tube 92 (FIG. 44). The reamer 126 is **rotated** with any suitable driver (such as driver 136 shown in U. ...FIGS. 1-6, a bone tap 142 is passed through the drill tube 92 and **rotated** to at least partially pretap the 5 bore (FIG. 45). The tap is then **removed** to expose a tapped bore 207 with the drill tube 92 remaining in place. The...

...the drill tube 92. The implant 10 is threaded into the bore 207 with the **implant** driver 164 by the surgeon **rotating** the driver 164 and advancing it into the drill tube 92. As disclosed in U...

...implant are oriented in a superior-inferior direction (@.e., the larger holes are facing the **vertebrae** 200,2001).
After the **implant** 10 is fully in place, the **implant** driver 164 is **removed** through the drill tube 92 (FIG. 47). The drill tube 92 is then **removed** . The dura 204 is retracted slightly and the centering guide 100 is then **removed** . The dura 204 is then retracted to the opposite side and the centering guide'002is repositioned with the disc space 204 but **rotated** 180' relative to FIG. 39 so that the rounded side 114, is facing both the...

...apparatus of the invention in a posterior approach. It will be noted that for placing **two** **implants** 10, the centering guide'002is **removed** and reinserted into the disc space 202 to reorient the guiding surface 1122When performing an...guiding surfaces 112,114 so that a first bore can be formed, tapped and an **implant** 10 **inserted** through the drill tube (FIG. 50). After the **implant** 10 is **inserted** , the centering guide 100 remains in place but the drill tube 92 is moved to the opposite side and guided 1 5 into **position** by the **second** guiding surface 114 (FIG. 51). With the drill tube 92 in **position** on the **second** side, a bore 206 is then formed by passing the reamer and tap through the drill tube and a **second** **implant** is **inserted** through the drill tube.

J. Lateral Approach
The present invention is particularly suited for a lateral approach where an elongated single **implant** is to be placed in the inner **vertebral** space. The present invention requires smaller access space to the disc space which is of...

...tube 92', whereas in the preferred embodiment previously disclosed, the drill tube 92 may be
rotated about its axis XD-XD'
From the foregoing detailed description of the present invention it...

Claim
1 A surgical method for implanting a **spinal** fusion **implant** into a disc
space **separating** a first **vertebra** and a **second** vertebra, said **method** comprising:
inserting a distal end of a rigid centering guide into said disc space with said guide...

...said disc space by insertion of said distal end into said disc space.

3 A **method** according to claim 2 comprising **inserting** said distal end from an anterior approach and selecting said distal end to have opposite ...

...an angle approximate to a desired angle of lordosis between said disc space.

4 A **method** according to claim 2 comprising **inserting** said distal end from a posterior approach and selecting said distal end to have opposite ...
...inserted by first inserting said distal end into said disc space with said side edges **rotated** to oppose said disc space and subsequently **rotating** said distal end within said disc space for said side edges to oppose and distract...

...includes said first
external guide surface and a second external guide surface, said first and **second** external guide surfaces **positioned** on opposite sides of said longitudinal axis with each of said first and second external...

...1 0 surface;
inserting a drill through said drill guide and boring a first bore;
inserting an **implant** into said first bore;
sliding a drill guide toward said **vertebrae** against said **second** guide surface;
1 5 **inserting** a drill through said drill guide and boring a **second**

bore; and **inserting** an **implant** into said **second** bore.

6 A method ...surface, said second surface being convex to present a smooth surface opposing a
dura, said **method** including:
retracting a dura before **inserting** said distal end into said disc space;
and
placing said distal end into said disc...

...with said second surface
opposing said dura.

7 An apparatus for use in implanting a **spinal** fusion **implant** into a disc
space **separating** a first **vertebra** and a second vertebra, said apparatus comprising:
a rigid centering guide having a distal end...

...includes said
first external guide surface and a second external guide surface, said first and **second** external guide surfaces **positioned** on opposite sides of said longitudinal axis with each of said first and second external...

...claim 7 wherein said guide includes a
plurality of x-ray detectable indicia at a **plurality** of **positions** at said distal end.
15 An apparatus according to claim

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00444104 **Image available**
INTERVERTEBRAL SPACER AND TOOL AND METHOD FOR EMPLACEMENT THEREOF
DISPOSITIF D'ECARTEMENT INTERVERTEBRAL, OUTIL ET PROCEDE POUR LE METTRE EN PLACE

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Detailed Description
Claims

Detailed Description
... a first of the vertebrae and the open bottom of the spacer being adjacent a **second** of the **vertebrae** . And in one particular form eL the present invention, this method can also comprise the **additional** step of: (iv) **inserting** a selected material between at least two of ...still further addressed by the provision and use of a method for emplacement of an **intervertebral spacer** , the method including the steps of: (i) providing an **intervertebral spacer** comprising an endless series of wall. elements collapsible, Lo a first configuration wherein a portion...elements are disposed :A the periphery of an enlarged body of the wall. elements; (ii) **inserting** the **spacer** in the first configuration between two **vertebrae** ; and (iii) expanding the **spacer** to the **second** configuration. And in another particular form of the present invention, Lh.i.s method can also comprise the **additional** step of: (i.v) **inserting** a selected material between at least two of the wall elements, wherein that material may ...present invention are still further addressed by Lhe provision and use of a method for **emplacement** of an intervertebral **spacer** , wherein the method includes providing an **intervertebral spacer** comprising an endless series of wall elements collapsible to a first: conf.i.quraL.ion...elements

are disposed at the periphery of an enlarged body of the wall elements. The **method** further includes providing an **inserter** tool having a first portion thereof for connection to a distal connector wall. element of...

...of the wall elements, the inserter tool's first portion being axially movable in Lhe **inserter** tool's **second** portion. The **method** still further includes the steps of: (i) connecting the inserter tool's **second** portion to the **spacer** 's proximal ...i.nserter tool's first portion to the spacer's distal connector wall element, and **positioning** the **spacer** in its collapsed configuration; (ii) extending the **inserter** tool and **spacer** through a pa L:i.en L' s body toward a space between two adjacent **vertebrae** while the **spacer** is in its collapsed conf:i guraLion; (M) placing the spacer in the aforementioned space **disconnecting** the inserter tool's first portion from the **spacer** ; (vi) **withdrawing** the **inserter** tool's first portion from time **spacer** ; (vii) disconnecting the **inserter** tool's **second** portion from the **spacer** ; and (viii,) **withdrawing** the **inserter** Lool from the **spacer** and from the patient' body

And in another particular form of the present invention, this...comprise fusion enhancing materials, therapeutic agents, artificial disc components, and the like. If desired, the **spacer** can be passed to the patient's **spine** by way of the patient's abdominal cavity .

The objects of the present invention are still further addressed by the provision and use of a **method** for **emplacement** of an inLervertebral **spacer** , the **method** comprising the steps of providing an inLervertebral spacer comprising a Lop apiece having a distal...plate extends toward the proximal plate and between the Lop and bottom pieces, to a **second position** in which the free edge of the distal plate is engaged in a groove in...engageable with the spacer dista]l plate to move the distal plate from the first **position** to the second **position** . The **method** still further includes the steps of placing the spacer in a condition in which the...

...to the spacer, directing a distal end of the spacer into a gap in a **spinal** column, driving the **spacer** into the gap, directing the rod through the tubular member and Lhe proximal plate hole...Lo move from the first position to the second position to expand the spacer, and **withdrawing** Lhe rod and **disconnecting** the tubular member from Lhe **spacer** , so as to leave the expanded **spacer** in the **spinal** . column gap. The method can include the addit i.onall step of injecting a selected...state and connected to an inserter tool;

Fig. 2 is a perspective view of the **spacer** of Fig. in **position** adjacent a **vertebra** and in an expanded state;

Fig. 3 is a side elevati.onal view of a...column of vertebrae, including a disc between a pair

of adjacent vertebrae, Enjid ,;Iiow.iiiy **removal** of a disc
Fig. 15 is a Lop plan view of the **spacer** and
insertion Lool of Fig. 1 adjacent- a **vertebrae** ;
Fig. 1.6 is a side elevationall view, partly in
section, of Lhe spacer of Vi-q. 1 being positioned in
place between **two** vertebrae while the **spacer** is in its
collapsed state;
Fig. 17 is a Lop plan view of the spacer...in a further retracted
position;
Fig. 20 is similar to Fig. 21, but shows the
inserter tool disconnecLed from Lhe **spacer** ;
.Fig. 21 is similar to Fig. 20, but with the
inserter tool having been completely **removed** from the
surgical site;
Fig. 22 is a Lop plan view of an alternative
embodiment...is a diagrammatic side elevational view
illustrative of another alternative embodiment of
spacer, with the **spacer** being deployed in place between
two vertebrae ;
Fig. 28 is a top plan view of a further
alternative embodiment of spacer;
Fig...39;
Fig. 42 is a diagrammatic illustration of means
employed in collapsing Lhe spacer for **removal** from' an
operative site;
Fig. 43 is a diagrammatic illustration showing the
manner of **inserting** the **spacer** in a **spinal** column;
Fig. 44 is a diagrammatic illustration of an
alternative configuration of Lop piece and...Embodiments
Referring first to Figs. 1 and 2, it will be seen
that an illustrative **intervertebral spacer** 40 includes
an endless series of wall elements 42 collapsible to a
first configuration 44...

...46 (Fig. 2) so as to form an
enlarged body of wall elements 42. An **inserter** tool 90
(Fig.].) for **spacer** 40 includes a first portion 92
comprising an innerr tube 94 connectable to one of...ability to place
spacer 40 into this folded first
configuration 44 (Fig. 1) allows the **spacer** to be
easily **introduced** into the patient's body and then
maneuvered to the surgical site, whereupon the spacer adapted for
connection to the **spacer** 's **second**
connection structure 66, as by threaded engagement
therewith. Thus, proximal connector wall element 62
may...

...Fig. 2)

In a surgical operation, a diseased or damaged
disc D (Fig. 14) is **removed** (wholly or in part) from
between two vertebrae Va, Vb using a standard tool ...not shown) made in
the front
wall of the abdominal cavity A. Upon completion of
removal (in whole or in part-) of the afflicted disc D,
there exists a space G between the vertebrae Va and Vb.
Both during and after **removal** of the afflicted disc D,
the space G may be maintained or widened by use...90, with spacer 40
attached thereto, is
then extended through the previously made incision.

The **spacer** 40 is **inserted** through the incision and carried toward the disc space G in its collapsed configuration 44 (Fig. 15). The **spacer** 40 is placed between the **vertebrae** Va, Vb, as shown in Fig. 16

The inserter tool's inner tube 94 is...and a knob 10.22 for moving inner tube 94
within outer tube 90. After **insertion** and expansion of **spacer** 40, any "jack" tool present at the surgical site may be **removed** so as to allow **vertebrae** Va and Vb to close on the expanded **spacer** 40. Once in place, the wall elements 42 of spacer 40, which preferably are made...sufficient "springiness"
to provide a shock absorption capability

It will be appreciated that, once the **spacer** is in place, **vertebrae** Va and Vb will form "roofs" and "floors" for **spacer** 40, so as to define a substantially closed volumetric interior space. Of course, natural variations...

...and Vb may
result in some gaps existing between the upper and lower surfaces of **spacer** 40 and the opposing faces of **vertebrae** Va and Vb. However, for the purposes of the present invention, **spacer** 40, taken in conjunction with **vertebrae** Va and ...region which communicates with substantially all of the two adjacent faces of the two adjacent **vertebrae** Va and Vb

.Once **spacer** 40 is in place between the **vertebrae** Va, Vb and positioned in its expanded state, inner tube is **disconnected** from first connection structure 60 of distal connector wall element 52. This may be done by **turning** knob 102 so that inner tube 94 is unscrewed from first connection structure 60 (Fig...

...of inner tube 94 is then moved rightwardly, as viewed in Fig. 18, to a **position** generally centrally of the **spacer** 40. The knob 102 (Fig. 1.) is then **removed** from inner tube 94 and replaced by connection to a reservoir (not shown) of viscous...is filled with the fluid material 106 and the inner
tube 94 is then completely **withdrawn** from **spacer** 40
In order to prevent viscous fluid 106 from leaking out through proximal connector wall...

...the. proximal connector
wall element 62 as distal end 104 of inner tube 94 is **withdrawn** from **spacer** 40. This prevents fluid ...that relatively small
openings between the elements of spacer 40, or between spacer 40 and **vertebrae** Va and Vb, will result in fairly modest leakage

The inserter tool's outer tube 98 is then **disconnected** from the second connection structure 66 (Fig. 20), leaving **spacer** 40 in place (Fig. 21)

Vertebrae Va, Vb will LliereaCLer fuse together on

account of **spacer** 40 and the fluid 106 contained therein. In this respect it will be appreciated that, inasmuch as the adjacent **vertebrae** Va and Vb, respectively, form the "ceiling" and "floor" for **spacer** 40, fusion will occur ...may be formed with ridges or other small projections, so as to help keep the **spacer** in **position** between **vertebrae** Va, Vb

In Figs. 22 and 23, ...sufficiently to permit insertion of spacer 40 therein. Upon removal of the jack, the upper **vertebra** Va settles down upon **spacer** 40, with the upper pin portions 72 setting into the **vertebra** Va. Similarly, the **spacer** 40 settles down upon **vertebra** Vb, with the lower pin portions 74 setting into vertebra Vb. The pin portions 72...Thus, though Llie approach through the abdominal cavity A is at an oblique angle, the **spacer** is **positioned** on the **vertebrae** generally similarly to **spacer** 40

In the foregoing embod i inentcs, the spacer is provided with male **screw** mounts for engagement with counterpart female **screw** mounts on the inserter tool. Of course, this construction could be reversed, so that the spacer is provided with female **screw** mounts for engagement with male **screw** mounts on the inserter tool

Alternatively, other mechanical linkages of the sort well known in the art could also be used for attaching the **spacer** to the **inserter** tool

In Figs. 31 and 32, there is shown an alternative embodiment comprising a spacer...in Fig. 1, and expandable to a second configuration, as shown in Fig. 31. The **spacer** is **emplaced** in the same mannerr as is spacer 40, and may be modified in a manner...

...foregoing embodiments, the inserter tool's inner tube 94 is intended to be used to **insert** fluid material 106 into the interior of the spacer. However, it should also be appreciated inner tube 94 is **withdrawn** from the **spacer** and from outer tube 98

In Fig. 33, there is shown another alternative embodiment of...

...out" so as to leave standing a rounded disc wall W. In this embodiment, the **spacer** 110 includes a **plurality** of wall elements 112 which are pivotally anchored at one end and movable through an...interior disk matter to a herniated nucleus pulposus N which may be impinging on a **spinal** nerve (not shown)

Once the **spacer** 1. 10 is in place, the tube 114 may be **disconnected** from the **spacer** 1.10 and used to inject the material 106 into Lhe area bounded by wall W and flexible element 116. Thereafter, tube 1.14 is **withdrawn**

As shown in Fig. 34, Lhe wall elements 112 alternatively may be rigid elements urged lower adjacent **vertebrae** Va, Vb. Such growth causes the spacer to fuse to the adjacent **vertebrae** so as to lock the two vertebrae together. Similarly, the material can comprise a biocompatible...pieces 122, 128 and toward proximal plate 139. The distal plate is movable to a **second position** (Fig. 39) in which distal plate free edge 144 is engaged in bottom piece groove 146. In the **second position** , distal plate 190 is generally parallel to proximal plate 139
Referring again to Figs. 35...However, when the spacer is expanded, as shown in Fig. 39, distal plate 140 is **removed** from a side plate blocking position and the spring-biased side plates 160 can spring depending from bottom piece 128. The
pins 170 are adapted to engage the neighboring **vertebrae** Va, Vb

The **spacer** 120 is made of a substantially rigid material of sufficient strength to maintain support between **vertebrae** Va, Vb. Preferably, the material of **spacer** 120 is bio-absorbable, further discussed hereinbelow

An inserter tool 180 is provided for **insertion** of the **spacer** 120 into a space between **vertebrae** Va, Vb. The inserter tool 180 includes an outer tubular member releaseably connectable to proximal...plate 134 by connecting means 66. As shown diagrammatically in Fig. 43, the wedge-shaped **spacer** 120 is **inserted** into the gap between **vertebrae** Va, Vb and is driven into the gap by force exerted on tubular member 182...
...jack is often used to spread vertebra
Va, Vb apart to permit insertion of a **spacer** . However, in use of the present embodiment, the wedge-shaped **spacer** 120 may be driven into the space between **vertebrae** Va, Vb

The rod 184 is then introduced into tubular member and moved axially LhereLli...into the side closure positions shown in Fig. 41. The rod 184 may then be **withdrawn** from the **spacer** 1.20 and tubular member 182, and the tubular member 182 **disconnected** from proximal plate 134 and withdrawn from the operative site, leaving spacer 120 in place. Typically, the **insertion** of two such **spacers** is required, the **spacers** being **positioned** essentially side by side

Preferably, the outer tubular member 182 ...and, in some instances, rod 184 are used to inject a selected material 106 into **spacer** 120 before **inserter** tool 180 is **removed** from the surgical site. When rod 184 is of a tubular structure, the material 106...
...into
spacer 120. When rod 184 is of a solid construction, rod 184 may be **removed** and the material flowed through tube 182. Alternatively, a **separate** tube (not shown) may be substituted for rod 1.84 and' used for injection

of described above with respect to foregoing embodiments of **spacers** , and is often of the type encouraging fusion of **vertebrae** Va, Vb

To that end, the openings 148 permit flow of the material upwardly and...

...spacer 120 to come into contact with adjacent surfaces of vertebrae Va, Vb. If the **spacer** is of bio-absorbable material, as may be preferred, the **vertebrae** , over time, gradually fuse to one another while the **spacer** gradually disappears, leaving the **vertebrae** fused together with no intermediary **spacer**

In the event that it is necessary to **remove** **spacer** 120, a hook-like snagger 190 (...in Fig. 35, whereupon spacer 120, in the contracted state, may be withdrawn from the **spinal** column

In the present invention, material 106 may comprise fusion-enhancing materials, therapeutic agents, artificial...shown so as to facilitate proximal opening of the spacer. Spacer 40A is deployed by **advancing** the collapsed **spacer** to the surgical site so that its distal connector wall element 52A resides in the...

...then holding the inserter tool's first portion 92A steady while pulling proximally on the **inserter** tool's **second** portion 96A so as to expand spacer 40A proximally toward the user, so as to...spacer closer to the structure which is to be avoided

There is thus provided a **spacer** for **insertion** between adjacent vertebrae. The **spacer** is collapsible to a first relatively small configuration for passage through an incision, and expandable...is further provided an inserter tool assembly. There is still further provided a method for **emplacing** an intervertebral **spacer** , wherein the approach to **spacer** **emplacement** may be undertaken through the abdominal cavity. In one preferred embodiment of the invention, the **spacer** is **positioned** in the patient's **spine** using an abdominal approach. It is also to be appreciated that the **spacer** can be **positioned** in the patient's **spine** using either a laparoscopic abdominal (anterior) approach or an "open incision" abdominal approach, with Lhe or oblique. Furthermore, it should be appreciated that the **spacer** can also be **positioned** in the patient's **spine** using a posterior (i.e., rear) approach. Again, such an approach can be via either...

...be either straight or oblique. Thus, the spaces. can be positioned in the patient's **spine** from essentially any direction, limited only by anatomical considerations

It is to be understood Lhat...

Claim

What Is Claimed Is:

1. An **intervertebrall spacer** comprising a multiplicity of interconnected wall elements collapsible to a first configuration wherein said wall...

...being open at a generally planar top and a generally planar bottom thereof.

2. An **intervertebral spacer** according to claim 1 wherein said wall elements each comprise a rigid, elongated member.

3. An **intervertebral spacer** according to claim 2 wherein said wall elements are each connected to other of said wall elements by a hinge construction.

4. An **intervertebral spacer** according to claim 3 wherein said wall elements are spring-biased so as'to spring outwardly from each other.

5. An **intervertebral spacer** according to claim 3 wherein said hinge construction comprises pivot pins.

6. An **intervertebral spacer** according to claim 1 wherein a portion of said wall elements each comprise a body **intervertebral spacer** according to claim 1 wherein said wall elements comprise elongated wall members pivotally interconnected at...wall members being adapted for disposal in said remainder of the disc interior.

9. An **intervertebral spacer** according to claim 1 wherein said wall elements comprise elongated wall members pivotally connected at a first end thereof.

10. An **intervertebral spacer** according to claim 9 wherein said **spacer** further comprises a self-biased flexible wall member pivotally connected to said elongated wall members.

11. An **intervertebral spacer** comprising an endless series of wall elements collapsible ...elements are disposed at the periphery of an enlarged body of said elements.

12. An **intervertebral spacer** according to claim wherein said wall elements each comprises a rigid, elongated member.

13. An **intervertebral spacer** according to claim wherein said wall elements each comprises a rod of straight portions, said rod being pivotally connected at both ends thereof to adjoining wall elements.

14. An **intervertebral spacer** according to claim wherein said wall elements are pivotally connected

by a hinge construction, and...

...at the ends
thereof such that said wall elements provide an endless
wall.
15. An **intervertebral spacer** according to claim
wherein said hinge construction comprises pivot
pins.

16. An : **intervertebral spacer** according to claim

1.5 wherein extensions of at least some of said pivot
pins...

...beyond said spacer to engage at least one
vertebra adjacent to said spacer.

17. An **intervertebral spacer** according to claim
wherein said wall elements include a distal
connector wall. element ...to
said disposition at said periphery of said enlarged
body of wall elements.

18. An **intervertebral spacer** according to claim
wherein said wall elements include a proximal
connector wall element pivotally connected...
...of said wall elements, said
proximal connector wall element being adapted for
connection to a **second** portion of said **inserter** tool,
said proximal connector wall element and said adjacent
ones of said wall elements comprising at least a
portion of said other of said wall elements.

19. An **intervertebral spacer** according to claim
wherein said adjacent ones of said wall elements are
each connected to one of said adjoining ones of said
wall elements.

20. An **intervertebral spacer** according to claim
wherein a portion of said wall elements each
comprises a body of...

...said wall elements are connected to one another by a
living hinge.

21. An intervertebral **spacer** and **inserter** tool
assembly comprising:
a **spacer** comprising a multiplicity of
interconnected wall elements collapsible to a first
configuration wherein said wall...adjacent one of said wall elements and
having a second connection structure thereon; and
an **inserter** tool comprising first and **second**
portions;
said first portion of said inserter tool
comprising a tube extending ...adjoining ones of said wall
elements into and out of said enlarged configuration;
and
said **second** portion of said **inserter** tool
comprising a tube connected to said second connection
structure of said proximal connector wall...

...portion
tube.

22. An assembly according to claim 21 wherein said first portion tube, when **detached** from said first connection structure of said distal ...tube is detachable from said second connection structure of said proximal connector wall. element, to **remove** said inserter tool from said body of wall elements.
26. An assembly according to claim...construction comprises pivot pins and at least some of said pivot pins extend beyond said **spacer** to engage an adjacent **vertebra** .

28. An assembly according to claim 26 wherein said hinge construction comprises a pivot pin...tube having a grip member fixed thereto by which said second portion tube may be **rotated** for said engagement with and disengagement from said second connection structure, and said first portion tube having a knob fixed thereto by which said first portion tube may be **rotated** for said engagement and disengagement from said first connection structure.

33. An assembly according to said enlarged body.

34. A method for **emplacement** of an intervertebral **spacer** comprising the steps of:
providing an **intervertebral spacer** comprising a multiplicity of interconnected wall elements collapsible to a first configuration wherein said wall...
...expanded arrangement being open at a generally planar top and a generally planar bottom thereof;
inserting said **spacer** in said'first configuration between **two vertebrae** ; and
applying a force to at least one of said wall elements to ...elements from said first configuration to said second configuration, with said open top of said **spacer** adjacent a first of said **vertebrae** and said open bottom of said spacer adjacent a **second** of said **vertebrae** .

35. A method according to claim 34 comprising the further step of inserting a selected fluid material between at least two of said wall elements when said **spacer** is in said **second** configuration.

36. A method according to claim 35 wherein said fluid material comprises granular material...to claim 34 further comprising the step of hollowing out an afflicted natural disc, and **inserting** said **spacer** into the hollowed-out portion of said natural disc, such that said bottom of said...the group consisting of liquids, pastes, gels, and substantially dry particulates.

43. A method for **emplacement** of an intervertebral **spacer** comprising the steps of:
providing an **intervertebral spacer** comprising an

endless series of wall elements collapsible to a first configuration wherein a portion...are disposed at the periphery of an enlarged body of said wall elements;
inserting said **spacer** in said first configuration between two **vertebrae** ; and
expanding said **spacer** to said **second** configuration.

44. A method in accordance with claim 43 comprising the further step of filling said **spacer** in said **second** configuration with a fluid material.

45. A method according to claim 44 wherein said fluid particulates.

46. A method for **emplacement** of an intervertebral **spacer** comprising the steps of:
providing an **intervertebral spacer** comprising an endless series of wall elements collapsible to a first configuration to provide a...wall element and connecting said tool first portion to said distal connector wall element, and **positioning** said **spacer** in said collapsed configuration;
extending said tool second portion, with said tool first portion therein, through a patient's body toward a space between two adjacent **vertebrae** , with said **spacer** in said collapsed configuration;
placing said **spacer** , while in said collapsed configuration, in said space;
manipulating said tool so as to move said spacer from said collapsed configuration to said expanded configuration;
disconnecting said tool first portion from said spacer and **withdrawing** said tool first portion from said spacer; and
disconnecting said tool **second** portion from said **spacer** and **withdrawing** said tool from said **spacer** and from the patient's body.
47. A method according to claim 46 comprising the...

...filling said expanded spacer with a fluid material flowed through said tool first portion, after **disconnecting** said tool first portion from said spacer and before **withdrawing** said tool first portion from said spacer.

48. A method according to claim 46 wherein said **spacer** is **advanced** into the patient's body through the abdominal cavity.

49. A method according to claim 46 wherein said **spacer** is **advanced** into the patient's body using a posterior approach.

50. A method according to claim 46 wherein said **spacer** is **advanced** laterally into the patient's body from one side of the patient's body.

51. A method forr **emplacement** of an intervertebral **spacer** comprising the steps of:

providing an **intervertebral** **spacer** comprising a **plurality** of elongated wall. elements and a flexible wall element pivotally connected together at a single...elements through a tube, and expandable upon emergence from the tube;
providing said tube for **introduction** of said **spacer** into a **spinal** column;
hollowing out an afflicted natural disc to leave a peripheral wall of said natural...is disposed between at least two of said wall elements;
disconnecting said tube from said **spacer** ; and
withdrawing said tube.

52. An inter. **vertebral** **spacer** comprising a top piece having a distal end and a proximal end, a bottom piece...plate extends toward said proximal plate and between said top and bottom pieces, to a **second** **position** in which said free edge of ...position in which said side plates are substantially parallel to said top piece to a **second** **position** in which said side plates ...54 further comprising upper pins upstanding from said top piece and adapted to engage a **vertebra** .

56. The **spacer** according to claim 54 further comprising lower pins depending from said bottom piece and adapted to engage a **vertebra** .

57. The **spacer** according to claim 54 wherein said **spacer** top and bottom pieces, distal and proximal plates, and side plates are ...with said distal plate to move said distal plate from said first position to said **second** position.

64. The **spacer** according to claim ...said one of said top piece and said bottom piece.

66. !
n intervertebral spacer and **inserter** tool assembly comprising:
an **intervertebra7l** **spacer** comprising:
a top piece having a distal end and a proximal end;
a bottom piece...plate extends toward said proximal plate and between said top and bottom pieces, to a **second** **position** in which said free edge of said distal plate is engaged in a groove in...position to said second position.
.67. A method for emplacement of an intervertebral spacer, the **method** comprising the steps of:
providing an **intervertebral** **spacer** comprising:
a top piece having a distal end and a proximal end;
a bottom piece...plate extends toward said proximal plate and between said top and bottom pieces, to a **second** **position** in which said free edge of said distal plate is engaged in a groove in first position to said **second** **position** ;

placing said **spacer** in a condition in which said distal plate is in said first position;
connecting said...

...to said spacer;
directing a distal end of said spacer into a gap in a **spinal** column;
driving said **spacer** into said gap;
directing said rod through said tubular member and said proximal plate hole...

...plate to move from said first position to said second position to expand said spacer. **position** to expand said **spacer** .
68b ". ...from the source and through the tube into said spacer. o said spacer.

70. An **intervertebral** **spacer** according to claim wherein said wall elements include a distal connector ...of said wall elements, said proximal connector wall element being adapted for connection to a **second** portion of said **inserter** tool, said proximal connector wall element and said adjoining ones of said wall elements comprising...connector wall element and said adjoining ones of said wall elements being movable by said **second** portion of said **inserter** tool from said internal disposition to said disposition at said periphery of said enlarged body of wall elements.
71. An **intervertebral** . **spacer** according to claim wherein said distal connector wall element and said adjacent ones of said...

34/3,K/162 (Item 162 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00426746 **Image available**
SPINAL SPACER
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SPINAL SPACER
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Detailed Description
Claims

English Abstract
Spinal spacers (20) are provided for fusion of a motion segment. The spacers include a load bearing...

Detailed Description
SPINAL SPACER
FIELD OF THE INVENTION
The present invention relates to **spacers** , compositions, instruments and methods for arthrodesis. In specific applications of the invention the spacers include bone grafts in synergistic combination with osteogenic compositions.

BACKGROUND OF THE INVENTION
Spinal fusion is indicated to provide stabilization of the **spinal** column for painful **spinal** motion and disorders such as structural deformity, traumatic instability, degenerative instability, and post-resection iatrogenic...

...injury. This normal bone healing response is used by surgeons to induce fusion across abnormal **spinal** segments by recreating **spinal** injury

conditions along the fusion site and then allowing the bone to heal. A successful...

...local bone. This biological environment is typically provided in a surgical setting by decortication, or **removal** of the outer, cortical bone to expose the vascular, cancellous bone, and the deposition of...

...treat an anomoly involving an intervertebral disc.

Intervertebral discs, located between the endplates of adjacent **vertebrae** , stabilize the **spine** , distribute forces between **vertebrae** and cushion vertebral bodies. A normal intervertebral disc includes a semi-gelatinous component, the nucleus...

...and confined by an outer, fibrous ring called the annulus fibrosis. In a healthy, undamaged **spine** , the annulus fibrosis prevents the nucleus pulposus from protruding outside the disc space.

Spinal discs may be **displaced** or damaged due to trauma, disease or aging. Disruption of the annulus fibrosis allows the...

...to as a herniated or ruptured disc. The extruded nucleus pulposus may press on the **spinal** nerve, which may result in nerve damage, pain, numbness, muscle weakness and paralysis. Intervertebral discs...

...dehydrates and hardens, the disc space height will be reduced leading to instability of the **spine** , decreased mobility and pain.

Sometimes the only relief from the symptoms of these conditions is a discectomy, or surgical **removal** of a portion or all of an intervertebral disc followed by fusion of the adjacent **vertebrae** . The **removal** of the damaged or unhealthy disc will allow the disc space to collapse. Collapse of the disc space can cause instability of the **spine** , abnormal joint mechanics, premature development of arthritis or nerve damage, in addition to severe pain...material was simply disposed between the adjacent vertebrae, typically at the posterior aspect of the **vertebrae** , and the **spinal** column was stabilized by way of a plate or rod spanning the affected vertebrae. Once...

...the development of a contiguous growth of bone to create a solid mass because the **implant** may not withstand the cyclic compressive **spinal** loads for the life of the 2 5 patient.

Many attempts to restore the **intervertebral** disc space after **removal** of the disc have relied on metal devices.

U,S, Patent No, 4,878,915...

...the cage. Subsidence, or sinking of the device into bone, may also occur when metal **implants** are implanted between **vertebrae**0 if fusion is delayed. Metal devices are also foreign bodies which can never be fully...imaging.

Various implants have been constructed from bone or graft substitute materials to fill the **intervertebral** space after the **removal** of the disc. For example, the Cloward dowel is a circular graft made by drilling...

...or
autogenic plug from the illium. Cloward dowels are bicortical, having porous cancellous bone between **two** cortical surfaces. Such **dowels** have relatively poor biomechanical properties, in particular a low compressive strength. Therefore, the Cloward **dowel** is not suitable as an **intervertebral** **spacer** without internal fixation due to the risk of collapsing prior to fusion under the intense cyclic loads of the **spine** .

Bone **dowels** having greater biomechanical properties have been produced and marketed by the University of Florida Tissue...

...and autograft present additional difficulties. Graft alone may not provide the stability required to withstand **spinal** loads. Internal fixation can address this problem but presents its own disadvantages such as the...implants
and bone grafts while capturing advantages of both. For example Unilab, Inc. markets various **spinal** **implants** composed of hydroxyapatite and bovine collagen. In each case developing an implant having the biomechanical...
...has remained for fusion spacers which stimulate bone ingrowth and avoid the disadvantages of metal **implants** yet provide sufficient strength to support the **vertebral** column until the adjacent vertebrae are fused.

SUMMARY OF THE INVENTION
In accordance with one aspect of the invention, **spinal** **spacers** and compositions are provided for fusion of a motion segment, The spacers include a load...

...dowels, D-shaped spacers
and cortical rings.

One object of the invention is to provide **spacers** for engagement between **vertebrae** which encourages bone ingrowth and avoids stress shielding. Another object of the invention is to provide a **spacer** which restores the **intervertebral** disc space and supports the **vertebral** column while promoting bone ingrowth.

One benefit of the **spacers** of the present invention is that they combine the advantages of bone grafts with the...
...detail of the threads of the dowel shown in FIG. 7.

FIG. 9 is an **insertion** device for **inserting** the **spacers** of this invention.

FIG. 10A is a side perspective view of the dilation of a...disc space.

FIG. 17 shows the tap used in FIG. 16.

FIG. 18 shows an **inserter** engaged to a **dowel** ,
FIG. 19 shows the **inserter** of FIG. 18 within a sleeve.

FIG. 20 depicts **insertion** of a **dowel** ,
FIG. 21 is a side perspective view of a dural retractor.

FIG, 22 is a...

...guide protector shown
in FIG. 22.

FIG. 24 is a partial cross-section of a **spine** showing
bilateral placement of **two** **dowels** .

FIG. 25 is a partial cross-section of a **spine** with a
cortical ring implanted.

FIG. 26 is a cortical ring packed with an osteogenic...

...FIG. 33 is a top elevational view of a collagen sponge.

FIG. 34 is an **implant** **insertion** device.

FIG. 35 is a D-spaced spacer of this invention having a
tool engaging...of
FIGS. 50 and 51.

FIG. 53 compares the compressive strength of a threaded
cortical **dowel** to in vivo **spinal** loads.

FIG. 54 compares the compressive strength of the load
bearing members of this invention...

...of this invention to fusion cages.
FIG. 56 compares the fatigue loading values for various
spinal **implants** in axial compression.

FIG. 57 is a side elevational view of a multi-axial
loading...

...is a front elevational view of the fixture shown
in FIG. 57,
FIG. 59 compares **insertion** torque values for threaded
cortical **dowels** and other threaded fusion spacers.

DESCRIPTION OF THE PREFERRED EMBODIMENT
For the purposes of promoting...

...The spacers of this
invention are not required to support the cyclic loads of
the **spine** for very long because of the quick fusion rates
which reduce the biomechanical demands on...

...spacer.

Therefore this invention capitalizes on the advantages of
graft while avoiding the disadvantages.

The **spinal** **spacers** of this invention include a load
bearing member sized for engagement within a space between...several

advantages that were previously only available with metal implants. Threads allow better control of **spacer insertion** than can be obtained with a smooth surface. This allows the surgeon to more accurately **position** the **spacer** which is extremely important around the critical neurological and vascular structures of the **spinal** column.

Threads and the like also provide increased surface area which facilitates the process of...

...the donor bone material and fusion. These features also increase post-operative stability of the **spacer** by engaging the adjacent **vertebral** endplates and anchoring the **spacer** to prevent expulsion.

This is a major advantage over smooth grafts. Surface features also stabilize...

...the osteogenic composition includes a substantially pure osteogenic factor in a pharmaceutically acceptable carrier. The **dowel** 10 includes a wall 12 sized for engagement within the **intervertebral** space IVS to maintain the space IVS. The wall 12 defines an outer engaging surface 13 for contacting the adjacent **vertebrae** . The wall 12 is preferably cylindrically so that the bone **dowel** 10 has a diameter d which is larger than the height h of the space...surfaces 23 so that the composition has maximum contact with the endplates of the adjacent **vertebrae** . Referring now to FIG.

4, the **spacer** 21 includes a solid protective wall 26 which is positionable to protect the **spinal** cord from escape or leakage of the osteogenic composition 30 within the chamber 25. In...

...composition 30 is disposed within the chamber 25 to contact the end plates of adjacent **vertebrae** when the **spacer** 20' is implanted between the **vertebrae** . This provides better contact of the composition with the end plates to stimulate osteoinduction. Various...for this approach In a preferred embodiment, a single barrel outer sleeve 76a is first **inserted** (FIG, 11B) followed by a **double** barrel outer sleeve 76b, (FIG. 12),, finally followed by the outer sleeve 76 (FIG. 13...

...of this tripartite sleeve system is to provide an enlarged working channel for preparing the **vertebrae** and implanting the fusion **spacer** . In the step shown in FIG. 14, a drill or reamer 77 (FIG. 15) is...

...The openings can be tapped (FIG. 16) with a tap 78 (FIG. 17) to facilitate **screw insertion** of the fusion **spacer** 10, although this step is not necessary.

The fusion spacer 40 is then engaged by...

...18 & 19) and extended through the outer sleeve 76 as shown in FIG. 13. The **spacer** is then **inserted** into the disc space IVS until the 'initial thread 47

contacts the bone opening as shown in FIG. 20. The implant driver 60 can then be used to **screw** thread the fusion **spacer** into the tapped or untapped opening formed in the **vertebral** and end plate E. Once the **dowel** 40 is properly **positioned** , the knob 68 of the tool 60 can be **turned** to **rotate** the threaded tip 65 and disengage the tip 65 from the hole 49 of the **dowel** 40. The **inserter** 60 and the sleeve 76 can be **withdrawn** from the surgical site leaving the dowel 40 in place. It is understood that in...

...tools are introduced posteriorly at the instrumented motion segment. This approach may require decortication and **removal** of **vertebral** bone to accept the outer sleeve 76, A dural retractor 80 as shown in FIG, 21 may be used to retract and protect the **spinal** cord and accessory tissues. The retractor 80 includes a handle 81 which preferably includes a...

...The end 83 preferably includes a curve 84 which is configured to safely cradle the **spinal** cord.

With the **spinal** cord safely retracted, a seat guide protector 85 (...taps can be inserted through the seat guide protector similar as described above, The fusion **spacer** 40 can be **inserted** through the protector 85 into the dilated disc space,
With either the anterior or posterior approaches, the **position** of the fusion **spacer** 40 with respect to the adjacent **vertebrae** can be verified by radiograph or other suitable techniques for establishing the angular relationship between the **vertebrae** . Alternatively, the preferred depth of **insertion** of the **spacer** can be determined in **advance** and measured from outside the patient as the **spacer** is **positioned** between the **vertebrae** . The depth of **insertion** of the fusion **spacer** can be ascertained using depth markings (not shown) on the implant driver 60.

The spacers...

...approaches. This system includes templates, trephines, dilators, reamers, ports and other devices required for laproscopic **dowel** **insertion** .

Bilateral placement of **dowels** 40 is preferred as shown in FIGS. 2 and 24. This configuration provides a substantial...

...which provides only a single chamber 55 for packing with osteogenic material 30, The dual **dowel** placement results in **two** chambers 25 that can be filled with an osteogenic composition. Additionally, osteogenic material 30 such...FIG, 26 or left in place
as shown in FIG, 28,
In another specific embodiment, **spacers** are provided for engagement between **vertebrae** as depicted in FIGS. 29
Spacers of this invention can be conveniently incorporated into current surgical procedures such as, the Smith...

...M.D., G.W. and R.A.

Robinson, M.D., "The Treatment of Certain Cervical- **Spine** Disorders By Anterior **Removal** Of The **Intervertebral** Disc And Interbody Fusion", J. Bone And Joint Surgery,. 40-A:607-624 (1958) and Cloward, M.D., R,B,, "The Anterior Approach For **Removal** Of Ruptured Cervical Disks", in meeting of the Harvey Cushing Society, Washington, D.C., April...

...endplates of the adjacent vertebral bodies to accept a graft after the disc has been **removed** . The endplates are generally prepared to be parallel surfaces with a high speed burr. The...to the first friction or vertebral engaging surface 137.

In one specific embodiment for an **intervertebral** disc replacement **spacer** , a hollow D-shaped **spinal** **spacer** is provided. The anterior wall 111 as shown in FIGS. 29-31 is convexly curved...

...geometry of the adjacent vertebral bone and specifically to the harder cortical bone of the **vertebrae** .

The D-shape of the **spacer** 110 also prevents projection of the anterior wall 111 outside the anterior aspect of the disc space, which can be particularly important for **spacers** implanted in the cervical **spine** .
In one specific embodiment shown in FIGS. 32 and 33, the D-shaped spacer 110...

...into Smith Robinson surgical fusion technique. After partial or total discectomy and distraction of the **vertebral** space, the surgeon prepares the end plates for the **spacer** 110 preferably to create flat posterior and lateral edges.

The spacer 110 fits snugly with...

...surfaces against the posterior and lateral edges which prevents medial and lateral motion of the **spacer** 110 into **vertebral** arteries and nerves. This also advantageously reduces the time required for the surgery by eliminating...

...gripping of the handle. A shaft 152 extends from the handle 151 and is generally **divided** into two portions: a solid portion 153 and a split jaw portion 154. The split...jaw portions 154 are movable from a fully opened position as represented by the fully **separated** position of the gripping surfaces 158. The split jaw portion 154 is closeable to a fully closed **position** in which the **two** jaws 156 are in contact with one another. In the fully closed position, the gripping surfaces, identified as 158' in FIG. 34, are **separated** by a distance sufficiently close to grip a hollow spacer 110 therebetween. In particular, the...

...embodiment, the gripping surfaces 158 are roughened or knurled to enhance the grip on the **spacer** 110.

The **inserter** 150 further includes a sleeve 160 that is concentrically disposed around shaft 152. Preferably the...

...As the jaws are pushed together, the gripping surfaces 158 engage and firmly grip a **spacer** 110 as described above. This **inserter** can then be extended percutaneously into the surgical site to implant a spacer 110 in the intra-discal space. Once the **spacer** is properly **positioned** , the sleeve 160 can be moved back toward the handle 151, so that the natural resilience of the two jaws 156 cause them to **spread apart** , thereby releasing the **spacer** 110. The **inserter** 150 can then be **withdrawn** from the surgical site with the jaws fully opened, or the sleeve can be advanced...

...device are disclosed in commonly assigned, pending U,S, Application Serial No, 08/697,784, **IMPLANT** INSERTION DEVICE. Metal **spacers** , **insertion** devices and **methods** relating to the same are disclosed in commonly assigned and co-pending applications: U.S. Patent Application Serial No.

08/603,675, **VERTEBRAL SPACER** and U.S. Patent Application Serial No. 08/603,676, **INTERVERTEBRAL SPACER** .

Alternatively, the **spacers** of this invention may be provided with a tool engaging hole for insertion such as...preferably includes a curved portion 224 that conforms to the curved anterior surface of the **spacer** . The **inserter** 220 also preferably includes a T-handle 228 for **spacer** control and **positioning** . Preferably the **inserter** 120 includes means for **rotating** the threaded tip 225. In FIG, 37, the knob 230 is engaged to the tip...

...shaft rotatingly mounted within the handle 221 and shaft 222.

In the use of the **inserter** 220, a **spacer** 170 is engaged to the threaded tip 225 with the curved portion 224 flush with the anterior wall 171. The **inserter** and **spacer** can then be extended percutaneously into the surgical site to implant the spacer in the intra-discal space. Once the **spacer** 170 is properly **positioned** , the knob 230 can be **turned** to **rotate** the threaded tip 225 and disengage the tip from the hole 174 of the **spacer** 110. The **inserter** 220 can then be **withdrawn** from the surgical site leaving the spacer 170 in place.

In preferred embodiments, the engaging surfaces of the **spacers** are machined to facilitate engagement with the endplates of the **vertebrae** and prevent slippage of the **spacer** as is sometimes seen with smooth graft prepared at the time of surgery. The spacer...

...engaging surfaces 201 include teeth 205 which provide biting engagement with the endplates of the **vertebrae** . In another embodiment (FIGS, 41 and 42), the **spacer** 210 includes engaging surfaces 211 machined to include one or more blades 212. Each blade...fill the interior, As with the folded sheet, the strips can be arranged within the **spacer** in **several**

orientations , Preferably, the osteogenic material, whether provided in a sponge, a single folded sheet or in...dried. The graft-BMP composition
can then be frozen for storage and transport.

Advantageously, the **intervertebral spacers** of the present invention may not require internal fixation. The spacers are contained by the...

...the
surrounding ligaments and muscles, and the disc annulus if it has not been completely **removed** . Temporary external immobilization and support of the instrumented and adjacent vertebral levels, with a cervical...and has a stainless steel vice and/or clamping fixture to hold grafts for cutting **dowels** . The graft can be **positioned** to within 0,00111 of an inch which creates dowel uniformity during the cutting process...

...the wall of
5 the dowels. In addition, sterile water is used to cool and **remove** debris from graft and/or **dowel** as the dowel is being cut (hydro infusion). The water travels down through the center...

...addition, the water aides in ejecting
the dowel from the cutter.

The marrow was then **removed** from the medullary canal of the dowel and the cavity cleaned to create of chamber...

...the anterior wall of the dowel. The hole is
then tapped to receive a threaded **insertion** tool.

EXAMPLE 3
BONE **DOWEL** SOAKED WITH rhBMP-2
A threaded dowel is obtained through the methods of Examples 1...

...is followed to obtain the
appropriate rhBMP-2 concentration. This dilution provides sufficient volume for **two** **dowels** . The dilutions are performed as follows.

1. Using a 5-cc syringe, transfer 4.0...the anterior wall of the spacer. The
hole is then tapped to engage a threaded **insertion** tool.

The chamber of the **spacer** is then packed with an osteogenic composition as described in EXAMPLE 4 or 5.

EXPERIMENTAL...

...for testing with an axial test fixture 300. Four (4) samples of the threaded cortical **dowel** were **inserted** into **two** prepared plastic (polyacetal polymer) **blocks** 301,302 having matching geometry with the threaded cortical dowels 40 as shown in FIGS...

...cortical dowels
provides for a significant safety factor compared to both

typical and maximum physiological **spinal** loading as shown in FIG. 53. These values range from 1000 N when standing to...are determined at various load levels. Resistance to fatigue is important to the performance of **spinal** **implants** . The **implant** must be able to withstand cyclic in vivo loading until fusion occurs, It is estimated...

...million
cycles simulates approximately 2 years of cyclic loading prior to fusion and ultimate complete **spinal** motion segment stabilization.

The fixture 300 (FIGS. 50-52) described in Example 11 for the...

...flexion-extension or multi-axial cyclic test fixture 310 was developed (FIGS. 57 and 58). **Dowels** were tested in **both** static and dynamic loading situations. The specially designed fixture applied complex, **multi** -axial loading to the **dowels** ,
The dowels were placed into pre-tapped plastic (polyacetal polymer) blocks 311,312. The plastic...

...and a bending moment is generated by the 7.6 cm
2 5 loading arm.

Two **dowels** were subject to a static load to failure in the test fixture. The maximum load...the dynamic, multi-axial runout value is above this maximum bending load value.

EXAMPLE 13
INSERTION TORQUE TESTING OF THREADED CORTICAL **DOWELS**
Benchtop testing was performed to study the **insertion** torque required to **insert** the **dowels** and to compare these values with that of threaded interbody fusion devices. Two (2) lumbar calf **spines** were used for the insertion torque testing. Due to size constraints, an 18 mm threaded cortical **dowel** was **inserted** into the lowest **two** lumbar levels of each **spine** . The disc spaces were dilated and the space was reamed and then tapped, A specially modified driver was used to place the **dowels** and measure the **insertion** torque.

RESULTS.
No damage was noted to any of the **dowels** upon examination after **insertion** . The average insertion torque value was found to be 0.78 N-m. The threaded...

...runout at a value above the maximum expected bending loads.

4. The torque required to **insert** the devices is comparable with that seen with threaded fusion cages. No damage to the threads or the **dowel** drive attachment were detected when **inserting** and revising the **dowels** .

Overall, the threaded cortical dowels possess the required biomechanical properties to facilitate

interbody fusion in the lumbar **spine** . Their physical strength well exceeds the expected physiological loading and is superior to other bone...out tests by making a cut 5 mm from the lateral end of the metal **implant** and a **second** cut 5 mm from the first this cut. This resulted in three sections per bone...

Claim

1 A **spinal** **spacer** comprising a load bearing member having a wall sized for engagement within a space between...

...bone dowel having a diameter larger than the height of the space between the adjacent **vertebrae** .

9 The **spacer** of claim 8 wherein said bone member defines a chamber and said bone graft is...

...second osteogenic composition to stimulate osteoinduction, said second composition packed within said chamber.

11 The **spacer** of claim 10 wherein said **second** composition has a length which is greater than a length of said chamber and said second composition is disposed within said chamber to contact the endplates of adjacent **vertebrae** when the graft is implanted between the **vertebrae** .

12 The **spacer** of claim 11 wherein said **second** osteogenic composition is selected from the group consisting of autograft, allograft, demineralized bone, calcium phosphate...

...at least two opposite bone engaging surfaces for contacting a corresponding one of the adjacent **vertebrae** when the **spacer** is implanted therebetween, at least one of said engaging surfaces defining surface roughenings.

15 The...wherein said tool engaging hole is threaded to receive a threaded implanting tool.

25 A **spinal** **spacer** comprising a load bearing member having a wall sized for engagement within a space between...

...chamber and said composition is disposed within said chamber to contact the endplates of adjacent **vertebrae** when the **spacer** is implanted between the **vertebrae** .

27 The **spacer** of claim 26 wherein said osteogenic factor is a purified bone morphogenic protein isolated from...a fatigue strength of at least 7000 N at five million cycles.

56 A hollow **spinal** **spacer** for engagement between **vertebrae** , comprising:
an anterior wall having a convexly curved anterior surface and opposite ends;
a posterior...

34/3,K/163 (Item 163 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00423680 **Image available**
SPINAL **FUSION** IMPLANT **AND** METHOD **OF** INSERTION **THEREOF**
IMPLANT **DE FUSION** SPINALE **ET SON PROCEDE D'INSERTION**
Patent Applicant/Assignee:
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Inventor(s):
LARSEN Scott W,
SHIKHMAN Oleg,
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SPINAL **FUSION** IMPLANT **AND** METHOD **OF** INSERTION **THEREOF**
IMPLANT **DE FUSION** SPINALE **ET SON PROCEDE D'INSERTION**
Fulltext Availability:
Detailed Description
Claims

English Abstract
A **spinal** fusion **implant** includes lower and upper plate members (1021, 1041, 102u, 104u) dimensioned for at least partial...

French Abstract
Implant de fusion **spinale** comprenant des elements de plaque superieurs et inferieurs (1021, 1041, 102u, 104u), dont la dimension...

Detailed Description
AND **METHOD** OF **INSERTION** THEREOF **SPINAL** FUSION **IMPLANT**
BACKGROUND,
1. Technical Field
The present disclosure relates generally to a surgical apparatus for fusing...e.g., discectomy, and replacement of the excised disc with biologically acceptable plugs or bone **wedges** . The plugs are driven between adjacent **vertebrae** to maintain normal **intervertebral** spacing and to achieve, over a period of time, bony fusion with the plug and...

...Vich discloses a cylindrical bone plug having a thread on its exterior, which 5 is **screwed** into a correspondingly dimensioned cylindrical bore drilled ...vertebral spacing

More recently, emphasis has been placed on fusing bone structures (i.e., adjoining **vertebrae**) with prosthetic cage **implants** . One fusion cage **implant** is disclosed in commonly assigned U.S. Patent No. 5,026,373 to Ray et...is directed to further improvements in the fusion of adjacent bone structures, e.g., adjacent **vertebrae** . In a preferred embodiment, an **implant** for **insertion** within an **intervertebral** space between adjacent **vertebrae** for supporting the **vertebrae** in predetermined spaced relation is disclosed. The **implant** includes lower and upper plate members dimensioned for at least partial insertion within the intervertebral...vertebrae in spaced relation during healing. The linkage

mechanism is preferably adapted to cause lateral **displacing** movement of at least one plate member upon actuation thereof such that contacting surfaces of...at least one opening
extending therethrough to permit bone ingrowth

In another preferred embodiment, an **implant** for **insertion** within the **intervertebral** space includes first and second plate members having engaging surfaces with discontinuities to engage vertebral...plurality of coiled spring members may be incorporated as well

In another preferred embodiment, an **implant** for **insertion** within the **intervertebral** space includes at least first and **second** supporting members dimensioned for **insertion** within the intervertebral space and having contacting surfaces for contacting vertebral end faces of the... support members to facilitate the absorption of compressive forces

In yet another preferred embodiment, the **implant** includes at least first and **second** support members having engaging surfaces for engaging vertebral end plates of the vertebrae, and a...first and second support members between the non-deployed and the deployed positions. An actuating **screw** transverses a bore defined in the carnming block and threadably engages a threaded bore associated with one of the first and second support members. The actuating **screw** is **rotatable** to cause corresponding movement of
the catnming block

BRIEF DESCRIPTION OF THE DRAWINGS
Preferred embodiments...

...the drawings wherein:
FIG. 1 is a perspective view of a preferred embodiment of the **implant** for facilitating **spinal** fusion constructed in accordance with the principles of the present
disclosure;
FIG. 2 is a perspective view with parts **separated** of the **implant** of FIG. 1;
FIG. 3 is a perspective view of the **implant** in a collapsed **position** ;
FIG. 4 is a view illustrating the **implant** in the collapsed **position** and
inserted within an **intervertebral** space defined between adjacent **vertebrae** ; FIG. 5 is an isolated view further depicting the **implant** **positioned** within
the **intervertebral** space;
FIG. 6 is a view similar to the view of FIG. 5 illustrating the **implant** in its
extended **position** supporting the adjacent **vertebrae** in spaced relation;
FIG. 7 is ...embodiment of the implant of
FIG. 1;
FIG. 8 is a perspective view with parts **separated** of the **implant** of FIG. 7 illustrating the first and second support members, support springs disposed between the...

...a flexible cover surrounding the support spring;
FIG. 9 is a sectional view illustrating the **implant** **positioned** within the
intervertebral space;
FIG. 10 is an isolated view illustrating a preferred arrangement for mounting the flexible...

...members;
FIG. 11 is a view similar to the view of FIG. 9 illustrating the **implant**

slightly compressed during normal flexural movement of the **vertebral** column; FIG. 12 is a perspective view of another alternate embodiment of the **spinal**
implant ;
FIGS. 13-14 are perspective view of the respective upper and lower support members of...

...articulating movement of the support members;
FIG. 15 is a side plan view of the **spinal** **implant** of FIG. 12 in the assembled condition;
FIG. 16 is a sectional view illustrating the **implant** **positioned** within the
intervertebral space;
FIG. 17 is a view similar to the view of FIG. ...socket arrangement; FIG. 18 is a side plan view of an alternate embodiment of the **spinal** **implant** of FIG. 12 incorporating a resilient layer disposed between the upper and lower support
member,
FIG. 19 is a sectional view illustrating the **implant** of FIG. 18 **positioned**
0 within the **intervertebral** space;
FIG. 20 is a view similar to the view of FIG. 19 illustrating articulating the **spinal**
implant ;
FIG. 22 is a perspective view with parts **separated** of the **implant** of FIG. 21 illustrating the upper and lower support members, and the camming mechanism disposed between the support members for selectively moving the first and **second** support members
between a retracted **position** and an extended position;
FIG. 23 is a sectional view illustrating the **implant** in the retracted **position**
positioned within the **intervertebral** space;
FIG. 24 is a view similar to the view of FIG. 23 illustrating the **implant** in
the extended **position** ;
FIG. 25 is a side plan view of another alternate embodiment of the **spinal**
implant ;
FIG. 26 is a cross-sectional view taken along the lines 26-26 of FIG...

...28 are views similar to the view of FIG. 26 illustrating adjusting motion of the **implant** during flexural movement of the **vertebral** column
15
DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT(S)
The apparatus of the present disclosure is intended for fusing adjacent bone structures and has particular application in the **spinal** fusion of adjacent **vertebrae** subsequent to a discectomy procedure. The apparatus may be implanted using any conventional surgical approach...utilizing minimally invasive or endoscopic surgical techniques currently being utilized to carry out discectomy and **spinal** **implant** procedures

Referring now to FIGS. 1-3, there is illustrated the apparatus constructed in accordance...of the component 104 relative to component 102. In this manner, the overall width of **implant** 100 may be varied to accommodate **vertebral** columns of various sizes or to increase or minimize the supporting capacity of the implant...

...each other via the tongue and slot arrangement to decrease the overall width of the **implant** 100 thereby permitting more lateral movement of the **vertebral** column during healing. On the other hand, support components 102, 104 may be moved away from each other to increase the overall width of the **implant** thereby providing a more stabilizing effect to the **vertebral** column
Referring ...shaped projections 112 extending from the contacting surfaces, which define pointed edges to penetrate the **vertebral** end faces to thereby resist tendency of the **implant** to move or become **dislodged** once ...Apertures 114, 116 permit bone ingrowth through their respective plates to facilitate fusion of the **implant** with the **vertebral** bodies

As best depicted in FIG. 1, linkage mechanism, identified generally by reference numeral 118...position shown in FIG. 1 where upper and lower plate portions are at their most **displaced** position and a collapsed position shown in FIG. 3

Referring now to FIGS. 4-5, the **implant** 100 is shown **positioned** within
the **intervertebral** space "i" defined between adjacent **vertebrae** "VI, V2". **Implant** 100 is typically **inserted** within the **intervertebral** space "i" subsequent to a discectomy procedure

Discectomy involves **removal** of a least a portion of the degenerated disc material with the use of the cutting instruments (not shown) e.g., scalpels, rongeurs, etc..
Prior to **insertion** , the width of **implant** 100 is adjusted by selectively
adjusting the relative positioning of support components 102, 104 through the tongue and slot arrangement in the manner discussed above. **Implant** 100, in its collapsed condition, is thereafter positioned within the **intervertebral** space "i" with the use of a grasping instrument (not shown). As mentioned, conventional anterior...be utilized. In the collapsed condition, implant 100 presents a reduced profile which facilitates its **insertion** . Once **implant** 100 is **inserted** and appropriately **positioned** , the linkage mechanisms 118 are actuated to **displace** upper plate portions 102u, 104u from lower plate portions 1021, 1041 to move the implant the end plates to securely fix the **implant** member within the **intervertebral** space. In the deployed or extended **position** of FIG. 6, **implant** 100 forms a strut between adjacent **vertebrae** "VI V2" supporting the vertebrae in desired spaced relation. Linkage mechanisms 118 sufficiently support components...

...118 may be locked in the deployed position by conventional arrangements such as with locking **screws** , etc... As shown, upper plate portions 102u, 104u are in general parallel relation with lower...may be packed with bone growth inducing substances as
known in the art prior to **insertion** to facilitate the fusion **process**
Referring now to FIGS. 7-8, there is illustrated an alternate embodiment of the **spinal** **implant** of the present disclosure. **Implant** 200 is intended to be used in a similar manner to that described in connection with **implant** 100 of FIG. 1, i.e., within the **intervertebral** space defined between adjacent **vertebrae** subsequent to a discectomy procedure. **Implant** 200 includes first and **second** plate members 202, 204 supported in 5 spaced relation by a plurality of coiled support...are correspondingly dimensioned to provide sufficient force to
withstand extreme compressive forces exerted by the **spinal** column

As best depicted in FIGS. 8-9, first plate 202 includes a plurality (e... to FIGS. 9-10, in conjunction with FIG. 8, a flexible cover 216 may be **positioned** about the periphery of **implant** 100 to enclose the coiled spring members 206. Cover 216 is preferably fabricated from a...220 formed in first and second plate members 202, 204

FIGS. 9 and 11 depict **implant** 100 **positioned** within the **intervertebral**
space "i" defined between adjacent **vertebrae** "VI V2". FIG. 9 illustrates **implant** 100 in a fully extended **position** corresponding to a minimal load exerted on the **vertebral** column. FIG. 11 illustrates **implant** 100 in a compressed condition when the **vertebral** column is subjected to a large compressive load with support springs 206 absorbing the load. In addition, in the **inserted** **position** of **implant** 200, pyramid-shaped projections 222 extending from ...204 penetrate the vertebral end plates of the "VI, V2" to facilitate mounting of the **implant** 200 within the **intervertebral** space "i", and to prevent the **implant** 200 from becoming **dislodged** prior to achieving full fusion with the adjacent
vertebrae "VI, V2"

Referring now to FIGS. 12-17 there is illustrated another alternate embodiment of the **spinal** **implant** of the present disclosure. **Spinal** **implant** 300 includes first and **second** support members 302, 304 which supportingly engage adjacent vertebrae "VI, V2" upon insertion within an ...328 and socket 332 define generally equivalent radii of curvatures

FIGS. 16 and 17 depict **spinal** **implant** 300 disposed within the **intervertebral** space "i" defined between adjacent **vertebrae** "V I, V2". As shown in FIG. 16, **implant** 300 supportingly contacts the upper and lower **vertebrae** "V I, V2" through the engagement of first support member 302 and second support member...

...Projections 326 extending from the upper and lower plate portions 316, 318 of first and **second** support members 302, 304 **penetrate** the **vertebral** end faces to assist in retaining the **implant** 300 within the **intervertebral** space "i" during healing

FIG. 17 illustrates the articulating movement of the first support member relative to the second support member 304 during movement of the **spine** . As shown, spherical ...332 to permit such articulating movement

FIGS. 18-20 depict an alternate embodiment of the **spinal** **implant** 300 of
FIGS. 12-17. This embodiment is similar in most respects to the implant now to FIGS. 21-24, there is illustrated another alternate embodiment of the **spinal** **implant** of the present disclosure. **Implant** 400 includes **two** support members, i.e., upper support member 402 and lower support member 404 having respective...

...pyramid-shaped projections 410 which facilitate engagement with the vertebral end plates of the adjacent **vertebrae** "V 1, V2" upon **insertion** within the **intervertebral** space "i" **Implant** 400 further includes a caroming arrangement for moving upper and lower support members 402, 404...416 of support member 402. The camming arrangement further includes a threaded element, e.g., **screw** 418, which traverses a bore 420 within camming block 412 and threadably engages an internal 424 formed in side plates 426. Support member 404 has a **pair** of correspondingly **positioned** apertures 428 formed in side plates 430.

A pin 432 traverses each slot and opening...

...support member 402 and lower support member 404

FIGS. 23-24 illustrate rotational movement of **screw** 418 and the consequent corresponding traversing movement of camming **block** 412. In particular, **rotation** of **screw** 418 in a clockwise direction causes the **screw** to advance within threaded bore 422 thereby **advancing** caroming **block** 412 in the direction indicated by the directional arrow in FIG. 24 and **displacing** upper support ...or teeth extend from the first plate member 508 and are dimensioned to penetrate the **vertebral** end faces to facilitate retention of the **implant** 500 within the **intervertebral** space. First plate member 510 of support member 504 is preferably

Claim

WHAT IS CLAIMED IS,

1. An **implant** for **insertion** within an **intervertebral** space between adjacent **vertebrae** for supporting the vertebrae in predetermined spaced relation, which comprises:
lower and upper plate members...engage the vertebral end faces with the lower and upper plate members supporting the adjacent **vertebrae** in spaced relation during healing.
15

2. The prosthetic **implant** according to claim 1 wherein the linkage mechanism is adapted to cause lateral **displacing** movement of at least one plate member upon actuation thereof such that the contacting surfaces ...

...the lower and upper plate members are in general parallel relation when in the deployed **position** .
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3. The prosthetic **implant** according to claim 2 wherein the contacting surfaces of the lower and upper plate members have discontinuities to engage the **vertebral** end plates.

4. The prosthetic **implant** according to claim 3 wherein the discontinuities are projections dimensioned for penetrating the **vertebral** end plates.

5. The prosthetic **implant** according to claim 3 wherein the lower and upper plate members each include at least7. The prosthetic **implant** according to claim 6 including **two** linkage mechanisms, a first of the linkage mechanisms interconnecting the first plate portions of th...

...a second of the linkage mechanisms interconnecting the second plate portions of the first and **second** support members.

8. The prosthetic **implant** according to claim 7 wherein the first and second plate portions are connected through a...

...arrangement, the tongue and slot arrangement adjustable to permit relative movement of the first and **second** plate portions.

9. An **implant** for **insertion** within an **intervertebral** space between

adjacent **vertebrae** for supporting the **vertebrae** in spaced relation during healing, which comprises an **implant** member including first and **second** support components, the support components being operatively connected and moveable relative to each other to...

...each support component including upper and lower plate portions with contacting surfaces for engaging respective **vertebral** end faces of the adjacent **vertebrae** .

10. An **implant** for **insertion** within an **intervertebral** space defined between adjacent **vertebrae** , comprising first and **second** plate members dimensioned for **insertion** within the intervertebral space, the first and second plate members having engaging surfaces ...relative movement thereof to accommodate variations in loads realized during normal flexural movement of the **vertebral** column.

11. The **implant** according to claim 10 wherein the resilient member is a coil spring member.

12. The ...implant according to claim 10 wherein the resilient member includes a resilient layer.

15. An **implant** for **insertion** within an **intervertebral** space defined between adjacent **vertebrae** for supporting the vertebrae in predetermined spaced relation during healing which comprises at least first and **second** supporting members dimensioned for **insertion** within the intervertebral space and having contacting surfaces for ...second member to permit articulating movement of the first member to accommodate movement of the **vertebral** column during healing.

16. The **implant** according to claim 15 wherein the contacting surfaces of
the first and second plate members...implant according to claim 15 further including a resilient
member disposed between the first and **second** support members.

19. The **implant** according to claim 18 wherein the resilient member includes a layer of sponge-like material.

20. An **implant** for **insertion** within an **intervertebral** space defined between adjacent **vertebrae** for supporting the vertebrae in predetermined spaced relation during healing, which comprises at least first and **second** support members dimensioned for **insertion** within the intervertebral space defined between adjacent vertebrae and having ... move the first and second support members between a non-deployed position and a deployed **position** .

21. The **implant** according to claim 20 wherein the camming member includes a camrning block having a camming the first and second support members between the non-deployed and the deployed **positions** .

22. The **implant** according to claim 21 including an actuating **screw** transversing a bore defined in the caroming block and threadably engaging a threaded bore associated with one of the first and second support members, the actuating **screw** **rotatable** to cause corresponding movement of the camming block.

34/3,K/166 (Item 166 from file: 349)
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APPARTUS AND METHOD OF INSERTING SPINAL IMPLANTS
APPAREIL ET PROCEDE POUR PLACER DES IMPLANTS SPINAUX
Patent Applicant/Assignee:
MICHELSON Gary Karlin,
Inventor(s):
MICHELSON Gary Karlin,
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Claims

Detailed Description
... SUBSTMUTE SHEET (RULE 26)
receive the spinal implant I. In the preferred embodiment of the **spinal implant**, the **implant** has been enhanced by the use of, application to, and filling with fusion promoting, enhancing, and participating substances and factors. Thus, the **implant** may be fully prepared for **insertion** as provided to the operating surgeon. However, at the present time, human bone is most...

...mechanism 312 is stable during the clockwise cutting procedure, and yet allows for the rapid **disconnection** of the two components once the cutting is completed.

Because of the high interference between...

...304, and the relative weakness of the cancellous bone being harvested, it is possible to **remove** the Trephine 300 while still SUBSTFTLITE SHEET (RULE 26) drilling, and to have it extract...

...core of bone would remain fixed at its base, then with the drive mechanism 308 **removed**, a corkscrew 408 shown in Figure 14C is introduced though the central opening of rear...

...portion 306 and it can no longer advance. As corkscrew 408 is continued to be **turned** further, it will cause the core of bone to be pulled is rearward, as in **removing** a cork from a wine bottle.

Trephine 300 has a barrel portion 304 continuous with...

...toothed portion 302 having an inner diameter just less than the inner diameter of the **spinal implant** I to be loaded.

Referring to Figure 14B. the Trephine 300 with its core of by **rotating** knob 332 counterclockwise such that the plunger 372 is pulled via the long threaded shaft...

...330 are then ic advanced longitudinally into diametrically opposed paired L slots 340 and then **rotated** clockwise to complete this assembly. At the other end of instrument 320, a **spinal implant** I is engaged through its female rectangular slot 364 by a rectangular protruding bar extending...

...a female aperture centered within the female slot 364 of the spinal implant. With the **spinal implant** I secured to end plug 324 and the opposite end of the implant I presenting...

...the open end of implant I.

Referring to Figure 15, as knob 332 is then **rotated** clockwise, the plunger 372 proximal the threaded shaft 328 is then forcibly, but controllably driven...

...SHEET (RULE 26) forward down the barrel 304 ejecting the bone graft directly into the **spinal implant** I. As the bone graft is greater in length than the interior of the **spinal implant** , with further compression the bone is forced into the radially disposed apertures through the wall...

...the device communicating from the central cavity to the exterior.

End plug 324 is then **removed** from apparatus 320. Using end plug 324 as a handle, end cap 374 shown in Figure 16 is secured to the open end of the **spinal implant** I. The **implant** is then disassociated from end plug 324 by **rotating** knob 334 counterclockwise.

Referring to Figure 16, an Implant Driver instrument which may be used to either **insert** or to **remove** said **implant** I is shown. Driver 350 has at its far end 362, a rectangular protrusion 398Threaded portion 353 **screws** into a female aperture central slot 364, urging 3S3 into 364, and binding them together such that instrument 350 can be **rotated** via paired and diametrically opposed extending arms 366 and in either direction while maintaining contact with the implant.

Referring to Figure 17, affixed to the Driver 350, the **implant** I is then **introduced** through the Outer

SUBSTITUTE SHEET (RULE 26)
Sleeve 140 and **screwed** into the interspace opposed between the two prepared **vertebrae** V until such time as the leading edge of the **Implant** Cap 374 reaches the depth of the prepared hole at which time its forward motion...

...drilled out. This allows for a progressive feel to the surgeon as the implant is **screwed** home.

As described previously, with the use of the Tap 280, this terminal resistance to...

...to the surgeon.

Again, as with the Tap 280, visual monitoring of the depth of **insertion** of the **implant** is provided to the surgeon by observing the progressive approximation of the forward surface 370...

...surface 172 of the Outer Sleeve 140, prohibiting any further installation of the 2 0 **spinal** **implant** .

Referring to Figure 18, once the **implant** has been fully installed, the Driver 350 is dissociated from the implant I by **turning** knob 354 in a counterclockwise direction. The Driver 350 is then **withdrawn** from the 25- Outer Sleeve 140, then the Outer Sleeve 140 is **removed** .

This leaves the **implant** fully installed and inset to the determined depth as shown in Figure 18.

Attention is then redirected to the other, or first, side of the **spine** . A dural nerve root retractor
SUBSTITUTE SHEET (RULE 26)
is used to retract the neural...
...of the Short Distractor 120, lying flush on the canal floor.

Utilizing apparatus 152, extended **screw** portion 116 is inserted into the female threaded portion 114 of the Short Distractor 120...

...152 is engaged to the female rectangular portion 118 of the Short Distractor 120. Then **turning** rearward facing portions 108 and 110, utilizing the knob 136 of Figure 2, the Long...

...Cap 162. The entire sequence of events as described for the implantation of the spinal **implant** I as already placed, is then repeated such that both **spinal** **implants** come to lie side by side within the interspace.

Though not necessary, circlage or other...PradIstracti=.- And Utilizing A -Guarded Sleeve
System Is Disclosed
Because of the absence of the **spinal** cord and
SUBSTITUTE SHEET (RULE 26)
nerve roots, it is generally possible to visualize in...

...width of the disc space from side to
side throughout the cervical, thoracic, or lumbar **spine** .

In the preferred embodiment of the anterior interbody fusion, **implants** are placed side by side from anterior to posterior parallel to the interspace and extending...

...the transverse
width of the disc space is insufficient to allow for the use of **two** **implants** , each of which would be large enough to protrude to the required depth into the adjacent **vertebrae** , then a singular and significantly larger **implant** may be placed centrally. With this in mind, and in light of the very detailed...

...in regard
to the method of posterior lumbar interbody fusion, a brief discussion of anterior **spinal** interbody fusion with dual **implant** installation will suffice, and the method for installation of a large, singular midline graft will become obvious.

The interspace to be fused is exposed
anteriorly. The soft tissues are **withdrawn** and protected to either side, and if necessary, above and below as well. It is...

...nuclear disc portion. (Alternatively,
SUBSTITUTE SHEET (RULE 26)
the disc can be left to be **removed** via the drill later.) The surgeon then notes and marks a point midway from side to side anteriorly. He then **inserts** Long Distractor 100 centering it on a point midway between the point just noted and...inserted, then its exact duplicate is inserted anteriorly equidistant to the other side of the **spine** .

As the barrel portion 106 of Long Distractor 100 is is exactly of the same major diameter as the **spinal** **implant** I looking coaxially on end, the surgeon can then asses the anticipated side by side...

...implanted.
Referring to Figures 7C and 7D, a Dual Outer Sleeve 340 consisting of a **pair** of hollow tubes is then **introduced** over the side by side Long Distractors 100 protruding anteriorly from the **spine** . The Dual Outer Sleeve 340 is comprised of two hollow tubular members identical in size **displaced** from each other ideally the sum of the difference between the minor and major diameters of **both** **implants** combined, but not less than that difference for one implant, as it is possible to...

...slightly greater than two times the
difference between the major and minor diameters of the **implant** (the sum of **both**) the distance may be considerably greater. Whereas in the preferred embodiment the paired tubular portions...

...may be
inclined or declined relative to each other such that

they either converge or **diverge** at their proximal ends.

The paired tubular portions 348, may be bridged in part or...rigidly held via
Foot Plate 344 and the prongs 342. Thus, it is possible to **remove** either one, or if desired, both of the Long Distractor rods utilizing Long Distractor puller...

...is then the
surgeon's choice to work on one or both sides of the **spine** . As per previous discussion, the surgeon may drill the interspace utilizing the Inner Sleeve 242...

...the Long Distractors in place as per the "Trephine Method".

Tapping, if necessary, and the **insertion** of the **implants** then occurs through the protective Outer Sleeve
SUBSTITUTE SHEET (RULE 26)
340. once the **implants** have been fully **inserted** , the outer Sleeve is **removed** .

Having utilized the Drill method, or "Trephine Method", with or without an Inner Sleeve to...

...that the surgeon wishing to
ability to directly visualize the tap being used, or the **implant** being **inserted** , may choose to **remove** the Outer Sleeve after the insertion of the first prosthesis to maintain stability, or prior...

...ed Pmbadiment Far
Method Of Anterior Interbody Fusion
As previously described for the posterior lumbar **spine** , alternatively, one can employ the "Trephine 2C Method" as has been described in detail.

As...the preferred
embodiment, it is nevertheless within the scope of this invention that one could **remove** the Outer Sleeve as there are no neural structures requiring protection, and **insert**
SUBSTITUTE SHEET (RULE 26)
the **implants** directly rather than through the Outer Sleeve.

As yet a further alternative of this method...

...depth into the
opposed vertebral bodies is such that it is not possible to place **two** such **implants** side by side, then only a single implant which may be of significantly increased diameter...

...drill or the "Trephine Method".

Referring to Figures 16-18, a cylindrical
embodiment of the **spinal** **implant** I of the present invention is shown. In Figure 16 the implant I is shown...

...18 the implant I is shown installed in the disc space D,

between the adjacent **vertebrae** .

The cylindrical **implant** I comprises a hollow tubular member which in the preferred embodiment is made of an...

...Detailed-Des-cri,p-tion of Alternative Embodiments.of Apparatus-and Method
When the human **spine** is viewed from the side, it consists of a balanced series of curves, as opposed...
...line when viewed from the side. In both the cervical and lumbar regions of the **spine** , the **vertebrae** relate to each other so as to form curves where the apex 2C of said curves is **displaced** forward within the body, and those segments of the **spine** are said to be in lordosis.

In contradistinction, in the thoracic portion of the **spine** , the **vertebrae** relate to each other so as to form a curve where the apex of said curve is **displaced** posteriorly and is said to be in kyphosis. The methods and instrumentation of the present...

...vertebrae in the correct anatomic lordosis or kyphosis. Where it is possible to approach the **spine** from various angles each of the devices, then has different forms appropriate to that specific...

...of restoring and maintaining lordosis of adjacent vertebrae V from the posterior approach of the **spine** is shown. The Posterior Long Lordotic Distractor 400 is inserted from the posterior aspect of the **spine** and comprises a barrel portion 410 terminating at its distal end 412 in a disc penetrating portion 420 which is shown interposed within the disc space between **two** adjacent vertebrae V. The disc **penetrating** portion 420 terminates distally into a leading bullet-shaped front end 422 which facilitates the backing out as the compressive forces of the **spine** upon the disc penetrating portion 420 tend to urge it forward, while simultaneously the circumferential...

...Posterior Long Distractor 400 exceedingly stable.

Referring to Figure 20, in preparation for the bone **removal** step, the Posterior Long Lordotic Distractor
SUBSTITUTE SHEET (RULE 26)
400 is shown with the...

...420 in place between the adjacent vertebrae V to restore and maintain lordosis of the **spine** . An Outer Sleeve 140 described above in reference to Figure 5, is properly seated over...
...Distractor 400 using a mallet and the already described Driver Cap 160.

While the bone **removal** step may be performed by either the drilling method described above in reference to Figures...

...the Posterior
Long Lordotic Distractor 400 undisturbed until sufficient space has been created by the **removal** of bone at least as great as the thickness of the wall of the trephine 270 itself to allow for the unobstructed **removal** of the Posterior Long Lordotic Distractor 400.

If the "Trephine Method" described above in reference...

...concentrically seated relative to the barrel portion 410, the Inner Sleeve 242 alone would be **removed** , and the trephine 270 would then be placed over the Posterior Long Lordotic Distractor 400...
...the saw-like sharp
cutting teeth 271 of the trephine 270 shown in Figure 11B **removes** a path of bone equal to the distance of the splaying out of each of...

...than the
wall thickness of the trephine 270 itself. Thus, once the trephine 270 is **removed** , left behind is a semi cylindrical space outlining each of the arcs of bone cut...21 and 22, since the
vertebrae V are placed into lordosis prior to the bone **removal** step, the space S created by the bone **removal** is cut at an angle relative to the vertebrae V in the shape of a...

...which corresponds to the shape of the
cylindrical implant I. In this manner, the cylindrical **implant** I with parallel walls may be inserted between adjacent **vertebrae** V which have been stabilized for fusion in angular relationship to each other so as to preserve the normal curvature of the **spine** .
Referring to Figures 23 and 24, an elevational
SU B STITUTE S H E ET...

...dural sac and nerves while work
is being performed on the contralateral side of the **spine** . If the Posterior Short Lordotic Distractor 500 were other than stable, injury to these structures...

...Referring to Figure 25, an Anterior Long
Lordotic Distractor 600 for use anteriorly within the **spine** is shown. It can be seen that the configuration of the disc penetrating portion 620...

...620.

The Anterior Long Lordotic Distractor 600 serves to restore and maintain lordosis of the **spine** by distraction of the adjacent **vertebrae** V. As described above for the Posterior Short Lordotic distractor 500, it is appreciated that...within the disc space and further held there by the considerable compressive loads within the **spine** .
Referring to Figure 28, because of the
stability thus provided, a further derivative advantage

is...

...with the vertebrae V and the extended portions 720 and 722 would ensure the proper **rotatory** alignment.

A further advantage, to be discussed in more detail subsequently, is that the extended...

...a Posterior Lordotic Extended Outer Sleeve 800 for use from the posterior approach of the **spine** is shown. The Posterior Lordotic Extended Outer Sleeve 800 comprises a hollow tubular member 802...and 822 are configured to restore and maintain lordosis
SUBSTMUTE SHEET (RULE 26)
of the **spine** similar to the disc penetrating portion 420 of the Posterior Long Lordotic Distractor 400, the...

...31, an Anterior Extended Outer Sleeve 900 for use from the anterior approach of the **spine** is shown. The Anterior Lordotic Extended Outer Sleeve 900 comprises a hollow tubular member 902...

...the extended portions 920 and 922 are configured to restore and maintain lordosis of the **spine** from the
SUBSTMUTE SHEET (RULE 26)
anterior approach similar to the disc penetrating portion 620...

...for use anteriorly is shown in the singular form and in use in the lumbar **spine** , it is understood that it may take a double barrelled form and in either form, be used throughout the **spine** .

Referring to Figures 33 and 34, a Lumbar Dual Extended Outer Sleeve is shown and...and 1102, in order
SUBSTITUTE SHEET (RULE 26)
to maintain the normal curvature of the **spine** by correcting the angular relationships of the vertebrae V.

The extended portion 1121, is tapered...
...for engaging the vertebrae V .

Each of the hollow tubular members 1101 and 1102 are **displaced** from each other ideally the sum of the difference between the minor and major diameters of two threaded **spinal implants** I combined, but not less than that difference for one implant I, as it is...

...have the threads of one implant I nest interposed to the threads of the other **implant** I such that they **both** occupy a common area between them. Typically, the walls of each hollow tubular members 1101...

...two hollow tubular members 1101 and 1102 may be placed closer together so that two **spinal implants** I may be placed closer together when I.nserted within the disc space between adjacent vertebrae

W. The hollow tubular member 1101 and 1102 can be overlapped or **displaced** from each other so as to control SUBSTITUTE SHEET (RULE 26) the distance between implants when the Dual Extended Outer Sleeve is utilized and **two** **implants** implanted The hollow tubular members 1101 and 1102 may be bridged in part or wholly...

...V, but limited in length so as not to over penetrate beyond the vertebrae once **inserted** .

Referring to Figure 35, a **second** Dual Extended Outer Sleeve 1200, is ...RULE 26) lordotic distractor for use posteriorly when referring to their use in the lumbar **spine** , would be used anteriorly if applied to the thoracic **spine** , either in the single or double-barrel form. This is because the thoracic **spine** is normally curved into kyphosis which is the reverse of lordosis. That is, in approaching the thoracic **spine** anteriorly, it would be desirable to distract the back of the disc space more than...

...Anterior Short Lordotic Distractors, though referred to previously as lordotic when placed into the lumbar **spine** from the posterior approach, would now more correctly, when placed in the thoracic **spine** from the anterior approach be called Kyphotic Thoracic Distractors.

It can readily be appreciated that...

...Figures 36-41, shown is the apparatus 1350 for use in installing an improved interbody **spinal** fusion **implant** 1300 having one or more SUBSTITUTE SHEET (RULE 26) flat sides as disclosed in co-pending application filed on February 17, 1995, entitled IMPROVED INTERBODY **SPINAL** FUSION **IMPLANTS** which is incorporated herein by reference. The apparatus 1350 comprises a Dual Outer Sleeve 1310...

...size and each having an internal diameter slightly larger than the outer diameter of the **spinal** fusion **implant** 1300. The cylindrical tubes 1352, 1354 are in communication with each other along their length and are **displaced** from each other ideally a distance that is slightly greater than the sum of the diameters of two **spinal** fusion **implants** 1300 placed side-by-side with the flat sides 1302 of each **spinal** fusion **implant** 1300 touching. The cylindrical tubes 1352 and 1354 are joined longitudinally such that they are...base of the adjacent vertebrae V.

Referring specifically to Figure 36, the apparatus 1350 is **introduced** over **two** Long Distractors !320 and 1322 placed side-by-side and protruding anteriorly from the vertebrae...

...held via foot plate
1360 and the prongs 1364a-1364f. Thus, it is possible to **remove** either one, or if desired, both of the long distractors 1320 and 1322. The dual outer sleeve has been described above for **inserting** **two** **implants** each having at least one flat side, may have extended portions SUBSTITUTE SHEET (RULE 26...

...Sleeve 1350 has been fully seated, one of the Long Distractors 1320 and 1322 is **removed** and the surgeon may drill the interspace D utilizing drill 250 using each of the...

...1354 to guide the drill 250 in
order to create overlapping holes in which the **spinal** fusion **implants** 1300a and 1300b may be **inserted** . It is also appreciated by those skilled in the art, that a hollow inner sleeve...that the tubular
members can be of a variety of shapes and sizes.

Further, the **removal** of disc and bone may be accomplished by the use of a burr, or a...

...the interspace D
has been drilled, an implant Driver 350 described above is used to **insert** the spinal fusion **implants** 1300a and 1300b preferably by linear advancement. The **implant** driver instrument 350 may be used to either insert or to SUBSTITUTE SHEET (RULE 26)
S
remove the spinal fusion implants 1300a and 1300b. Once affixed to the **implant** Driver 3SO, the **spinal** fusion **implant** 1300a is then **introduced** through one of the hollow cylindrical tubes 13S2,13S4 and driven into the interspace D...

...the application of an impaction
force transmitted through the implant driver instrument 350. once the **spinal** fusion **implant** 1300a is **inserted** into the interspace D, the surface roughenings of the outer surface of the spinal fusion...

...the bone of the vertebrae V and the implant Driver 350 is detached from the **spinal** fusion implant 1300a. The **implant** driver instrument 350 is then **withdrawn** from the Dual Outer Sleeve 1350 and the **spinal** fusion **implant** 1300a is fully installed and inset in the interspace D as shown in Figure 41.

Once a first spinal fusion **implant** 1300a is inserted into the interspace D, a second **spinal** fusion **implant** 1300b is driven into the interspace D so that the flat side 1302a or 1302b of each **spinal** fusion **implant** 1300a and 1300b are adjacent to each other and are touching. In this manner, two **spinal** fusion **implants** 1300a and 1300b are implanted within the interspace D and engage the bone of the adjacent vertebrae V without exceeding the width of the **spinal** column. It is appreciated that there are other ways that two **spinal** **implants** can have complimentary shapes and that they can

be inserted by linear **advancement** through a single (**both** at once) or dual outer sleeve having intradiscal extended members for stabilization, distraction, and/or...

...the present invention has been described in association with the implant of a threaded spinal **implant** , it is recognized that other forms of **implants** may be used with the present method. For example, dowels, made from bone or artificial materials, knurled or irregularly shaped cylinders or partial cylinders, or any other shaped **implants** that can be **introduced** through the outer sleeve may be used. Being able to perform the procedure through the...

Claim

1 Apparatus for use in **spinal** fusion surgery comprising a hollow tubular member having at least a first extended portion for **insertion** in the disc space between **two** adjacent vertebrae, said first extended portion providing distraction and alignment of said two adjacent vertebrae...

...vertebrae.

11 The apparatus of claim 10 in which said bone engaging means comprises a **plurality** of teeth for **insertion** into said adjacent vertebrae.

12 The apparatus of claim 10 in which said bone engaging...

...vertebrae.

13 The apparatus of claim I further including penetration preventing means for preventing over **penetration** of said **pair** of extended portions.

14 The apparatus of claim 1 including a **removable** hollow inner tubular sleeve.

15 The apparatus of claim 14 in which said inner sleeve...

...larger than the outside diameter of said increased diameter portion of said member.

18 A **spinal** distractor, comprising a disc penetrating portion for insertion in the disc space
SUBSTITUTE SHEET (RULE 26)
between adjacent vertebrae, said disc penetrating portion having an uneven diameter.

19 The **spinal** distractor of claim 18 including a barrel member extending from said disc penetrating portion.

20 The **spinal** distractor of claim 19 including a shoulder at the juncture of said ...barrel member for preventing said barrel member
from entering the disc space.

ic 21. The **spinal** distractor of claim 18 in which said disc penetrating portion includes a bullet-shaped front end to facilitate insertion in the disc space.

22 The **spinal** distractor of claim 18 in which said uneven diameter of said disc penetrating portion is...

...its proximal end and greater in a direction toward its distal insertion end.

23 The **spinal** distractor of claim 22 in which said disc penetrating portion includes a bullet-shaped front end at said distal insertion end to facilitate insertion into the disc space.

24 The **spinal** distractor of claim 18 in which said uneven diameter of said disc penetrating portion is...

...end at said distal insertion end to facilitate insertion in the disc space.

26 The **spinal** distractor of claim 19 in which said
SUBSTITUTE SHEET (RULE 26)
0 0
barrel member is **removably** attached to said disc penetrating portion.

27 The **spinal** distractor of claim 26 in which said disc penetrating portion includes a head portion for...

...pair of hollow tubular extended outer sleeves and having at least one extended portion for **insertion** in the disc space between **two** adjacent vertebrae.

29 The apparatus of claim 28 in which said hollow tubular member includes...

...SUBSTITUTE SHEET (RULE 26)
of hollow tubular members have at least one extended portion for **insertion** in the disc space between **two** adjacent vertebrae.

36 The apparatus of claim 34 in which said hollow tubular members include...attached to said hollow tubular members.

41 A method for inserting a spinal implant between **two** adjacent **vertebrae** comprising **inserting** a hollow tubular extended outer sleeve having means for engaging the **spine** ; **removing** at least a portion of a spinal disc located between two adjacent vertebrae; inserting an **implant** in the **vertebrae** through said tubular extended outer sleeve; and then **removing** said tubular extended outer sleeve.

42 The method of claims 42 in which said means for engaging the **spine** includes at least one extended portion for **insertion** in the disc space between **two** adjacent vertebrae.

43 The method of claim 42 including the steps of passing a boring...

...disc

SUBSTITUTE SHEET (RULE 26)

space and into a portion of the two adjacent vertebrae; **removing** the boring means.

44 The method of claim 43 in which said boring means is...

...is trephine.

46 The method of claim 41 in which said step for inserting an **implant** comprises **inserting** one or more at least partially cylindrical implants.

47 The method of claim 43 further including the step of inserting a **removable** hollow inner sleeve into said hollow tubular extended outer sleeve prior to passing said drill...

...during at least a portion of said method.

52 A method for inserting a spinal **implant** between two adjacent **vertebrae** , comprising the steps of:

inserting a **spinal** distractor in the disc space between two vertebrae to provide for proper spacing of

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the disc space between the vertebrae, said **spinal** distractor comprising a barrel member terminating in a disc penetrating portion having an uneven diameter;

inserting over the **spinal** distractor a hollow tubular member having at least a first extended portion for maintaining distraction of the adjacent vertebrae, said extended portion having an uneven height;

removing the **spinal** distractor from the hollow tubular member;

passing a boring means through the hollow tubular member...

...in the disc and a portion of the two adjacent vertebrae;

removing the boring means;

inserting an **implant** in the **vertebrae** through is the hollow tubular member; and

removing said hollow tubular member.

53 The method of claims 52 in which said boring means...of claim 52 in which said uneven diameter of said disc penetrating portion of said **spinal** distractor is greater proximate said barrel member and lesser in the direction away from said...

...penetrating portion in the disc space.

62 A method for inserting a spinal implant between **two** adjacent vertebra comprising:

inserting a **spinal** distractor having a disc

penetrating portion with an uneven diameter in the disc space between...

...to restore and maintain the normal angular relationship of the adjacent vertebrae;
placing over said **spinal** distractor and engaging to the **spine** a hollow tubular member having an engagement means for engaging the **spine** and for maintaining distraction of the adjacent vertebrae;
passing a trephine through the hollow tubular member and over the **spinal** distractor to drill a hole across the
SUBSTITUTE SHEET (RULE 26)
0 5
disc space...

...portion of the two adjacent vertebrae;
removing the trephine;
removing the spinal distractor;
inserting an **implant** in the **vertebrae** through the hollow tubular member; and
removing said hollow tubular member.

63 The method of claim 62 in which said trephine has...

...associated therewith for limiting the depth of the drilling.

64 A method for inserting a **spinal** **implant** between two adjacent **vertebrae** , comprising the steps of:
inserting at least one **spinal** distractor in the disc space between two vertebrae to provide for proper spacing of the disc space between the vertebrae;
inserting over said **spinal** distractor a **pair** of hollow tubular extended outer sleeves, said hollow tubular extended outer sleeves having at least one extended portion for **insertion** in the disc space between **two** adjacent vertebrae for maintaining distraction of the adjacent vertebrae;
removing said **spinal** distractor from said pair of hollow tubular extended outer sleeves;
passing a drill through each...

...the disc space and into a portion of the two adjacent vertebrae;
removing the drill;
inserting at least one **implant** into the
SUBSTITUTE SHEET (RULE 26)
0 6
vertebrae through said pair of hollow tubular extended outer sleeves; and
removing said pair of hollow tubular extended outer sleeves.

65 The method of claim 64 in...

...has an uneven height.

68 The method of claim 64 in which each of said

plurality of **implants** is cylindrical.
is 69. The method of claim 64 in which said **spinal** distractor has a disc penetrating portion with an uneven diameter.

70 The method of claim...

...engaging the
adjacent vertebrae.

78 A method for inserting a spinal implant between two adjacent **vertebrae** comprising **inserting** a **pair** of hollow tubular extended outer sleeves, said hollow tubular extended outer sleeves having at least one extended portion for **insertion** in the disc space between **two** adjacent vertebrae for maintaining distraction of the two adjacent vertebrae; passing a drill through each...

...to
drill holes across the disc space and into a portion of the two adjacent **vertebrae** ; **removing** the drill; inserting a plurality of **implants** into the **vertebrae** ; and **removing** said pair of tubular extended outer sleeves.
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0 8

79 The...

...part cylindrical.

80 The method of claim 80 further including the step of insertion a **removable** hollow inner sleeve into each of said pair of hollow tubular extended outer sleeves.
81...said hole is
drilled through a hollow inner sleeve and said hollow inner sleeve is **removed** prior to tapping said hole.
SUBSTMUTE SHEET (RULE 26)
I 0 9

90 The method...

...diameter of the implant.

92 A method for inserting a spinal implant between two adjacent **vertebrae** comprising the steps of:
(1) inserting a first distractor in the disc space between the two adjacent vertebrae and **inserting** a **second** distractor beside said first distractor to provide for proper spacing of the disc space between...

...and second
distractors a hollow tubular member having means for engaging said two vertebrae;
(3) **removing** said first distractor;
passing a drill through said hollow tubular member to drill a hole...

...the disc and a portion of the
two adjacent vertebrae;

(4) removing the drill;
(5) **inserting** an **implant** in the **vertebrae** through said hollow tubular member;
(6) **removing** said hollow tubular member;
(7) **removing** said second distractor; and
repeating steps (3) through (6).

93 A method for securing a hollow tubular sleeve to two adjacent vertebrae comprising:
inserting at least one **spinal** distractor into
SUBSTITUTE SHEET (RULE 26)
the disc space intermediate two adjacent vertebrae, said distractor...

...and as an
alignment rod for said outer sleeve;
driving said outer sleeve towards the **spine** over said distractor to engage said engaging means to the **spine** ; and
removing said distractor with a distractor pulling means leaving said outer sleeve in place.

94 The...which said
penetration preventing means is lockably adjustable.

96 A method for inserting a spinal **implant** between two adjacent **vertebrae** , comprising the steps of:
inserting a **spinal** distractor in the disc space between two vertebrae to provide for proper spacing of the disc space between the vertebrae, said **spinal** distractor comprising a barrel member terminating in a disc penetrating portion;
inserting over the **spinal** distractor a hollow tubular member having at least a first extended portion for maintaining distraction of the adjacent vertebrae, said extended portion having an uneven height;
removing the **spinal** distractor from the hollow
SUBSTITUTE SHEET (RULE 26)
tubular member;
passing a boring means through...
...in the disc and a portion
of the two adjacent vertebrae;
removing the boring means;
inserting an **implant** in the **vertebrae** through the hollow tubular member; and
removing said hollow tubular member.

97 The method of claims 96 in which said boring means...

...member increases in a direction away from said hollow tubular member.
103. A method for **inserting** a **plurality** of partially cylindrical spinal fusion **implants** made of a material appropriate for human implantation, each of said **plurality** of **implants** comprising a cylinder having a
SUBSTITUTE SHEET (RULE 26)
longitudinal central axis and at least...

...of:

drilling two partially overlapping cylindrical holes across the disc space between the two adjacent **vertebrae** ;
inserting a first of said partially cylindrical spinal fusion **implants** having a first flat side into one of said overlapping cylindrical holes, said first flat side being oriented perpendicular to the plane of said disc space;
inserting a **second** of said partially cylindrical **implants** having a **second** flat side into a second of said overlapping holes, said second flat side being adjacent...

...side
of said first implant.
104. A method for inserting a plurality of partially cylindrical **spinal** fusion **implants** made of a material 2C appropriate for human implantation, each of said **plurality** of **implants** comprising a cylinder having a longitudinal central axis and at least one flat side parallel...said disc space being in a plane perpendicular to the longitudinal vertical axis of the **spinal** column, comprising the steps of:
drilling two partially overlapping cylindrical holes across the disc space...

...adjacent
SUBSTITUTE SHEET (RULE 26)
vertebrae;
inserting a first of said partially cylindrical spinal fusion **implants** having a first flat side into one of said overlapping cylindrical holes, said first flat side being oriented perpendicular to the plane of said disc space;
inserting a **second** of said partially cylindrical **implants** having a **second** flat side into a second of said overlapping holes, said second flat side being adjacent...

```
Set     Items   Description
S1     276743   VERTEBR???? OR INTERVERTEBR???? OR INTERSPINAL?? OR INTERS-
             PINOUS?? OR SPINE? ? OR SPINAL OR SPINOUS OR BACKBONE? ? OR B-
             ACK()BONE? ?
S2     243921   BLOCK? ? OR BONEBLOCK? ? OR CHOCK? ? OR WEDGE? ? OR IMPLAN-
             T? ? OR INSERT? ? OR DOWEL? ? OR SPRAG? ? OR SWAGE? ? OR SHIM?
              ? OR SPACER? ? OR SPACING()ELEMENT? ?
S3     499215   INSERT???? OR EMPLAC????? OR ADVANC????? OR INTRODUC????? -
             OR INFIX??? OR EMBED???? OR IMBED???? OR SANDWICH????
S4     278548   PENETRAT???? OR INTERSPERS???? OR POSITION??? OR (CUT OR C-
             UTS OR CUTTING OR STICK??? OR PUT OR PUTS OR PUTTING)()IN
S5     456773   SEPARAT???? OR DIVID??? OR DIVERG??? OR DETACH??? OR DISUN-
             IT??? OR DISPLAC??? OR DECOUPL??? OR DISJOIN??? OR DISCONNECT-
             ???
S6      44440   PARTITION??? OR SEGREGAT??? OR (CAM OR CAMS OR CAMMED OR C-
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S7     459019   ROTAT???? OR TWIRL??? OR TURN??? OR SPIN???? OR REVOLV??? -
             OR SCREW??? OR CIRCUMVOLV??? OR ORIENTAT???? OR GYRAT????
S8     314451   REMOV???? OR WITHDRAW??? OR DISLODG??? OR EXTIRPAT???? OR -
             EVACUAT???? OR (TAKE? ? OR TAKING OR TOOK)()AWAY
S9    3146541   TWO OR TWIN OR DOUBLE OR SECOND OR BOTH OR PAIR OR 2ND
S10   1453088   PLURAL???? OR SEVERAL OR MULTITUDE OR MULTIPLE OR MULTI OR
             MANY OR ADDITIONAL OR NUMEROUS OR SPARE OR EXTRA OR MORE()THA-
             T()ONE
S11   2356217   METHOD? ?
S12   1260242   SYSTEM? ?
S13    643443   PROCESS??
S14    492561   PROCEDURE? ?
S15    867159   TECHNIQUE? ?
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             S11:S15
S17         6   S16 AND PY<1999
S18         6   RD (unique items)
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File 155:MEDLINE(R) 1966-2004/Mar W1
         (c) format only 2004 The Dialog Corp.
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             ACK()BONE? ?
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              ? OR SPACER? ? OR SPACING()ELEMENT? ?
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S4     255971   PENETRAT???? OR INTERSPERS???? OR POSITION??? OR (CUT OR C-
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S5     416981   SEPARAT???? OR DIVID??? OR DIVERG??? OR DETACH??? OR DISUN-
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             ???
S6      46028   PARTITION??? OR SEGREGAT??? OR (CAM OR CAMS OR CAMMED OR C-
             AMMING OR SPREAD??? OR URGE? ? OR URGING)()APART
S7     376804   ROTAT???? OR TWIRL??? OR TURN??? OR SPIN???? OR REVOLV??? -
             OR SCREW??? OR CIRCUMVOLV??? OR ORIENTAT???? OR GYRAT????
S8     305552   REMOV???? OR WITHDRAW??? OR DISLODG??? OR EXTIRPAT???? OR -
             EVACUAT???? OR (TAKE? ? OR TAKING OR TOOK)()AWAY
S9    2891625   TWO OR TWIN OR DOUBLE OR SECOND OR BOTH OR PAIR OR 2ND
S10   1353720   PLURAL???? OR SEVERAL OR MULTITUDE OR MULTIPLE OR MULTI OR
             MANY OR ADDITIONAL OR NUMEROUS OR SPARE OR EXTRA OR MORE()THA-
             T()ONE
S11   1216027   METHOD? ?
S12   2233505   SYSTEM? ?
S13    494440   PROCESS??
S14    469647   PROCEDURE? ?
S15    651775   TECHNIQUE? ?
S16        14   S1 AND S2 AND S3:S4 AND S5:S6 AND S7 AND S8 AND S9:S10 AND
             S11:S15
S17         7   S16 AND PY<1999
S18         7   RD (unique items)
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File  73:EMBASE 1974-2004/Mar W1
         (c) 2004 Elsevier Science B.V.
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S2     156424   SPINE? ? OR SPINAL OR SPINOUS
S3      14897   BACKBONE? ? OR BACK()BONE? ?
S4       3970   INTERVERTEBR????
S5      27109   VERTEBRA OR VERTEBRAE OR VERTEBRAL OR VERTEBRAS
S6     205711   BLOCK? ? OR BONEBLOCK? ? OR CHOCK? ? OR WEDGE? ? OR IMPLAN-
            T? ? OR INSERT? ? OR DOWEL? ? OR SPRAG? ? OR SWAGE? ? OR SHIM?
             ? OR SPACER? ? OR SPACING()ELEMENT? ?
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S8     298801   PENETRAT???? OR INTERSPERS???? OR POSITION??? OR (CUT OR C-
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S9     528666   SEPARAT???? OR DIVID??? OR DIVERG??? OR DETACH??? OR DISUN-
            IT??? OR DISPLAC??? OR DECOUPL??? OR DISJOIN??? OR DISCONNECT-
            ???
S10     77625   PARTITION??? OR SEGREGAT??? OR (CAM OR CAMS OR CAMMED OR C-
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            OR SCREW??? OR CIRCUMVOLV??? OR ORIENTAT???? OR GYRAT????
S12    318207   REMOV???? OR WITHDRAW??? OR DISLODG??? OR EXTIRPAT???? OR -
            EVACUAT???? OR (TAKE? ? OR TAKING OR TOOK)()AWAY
S13   3233981   TWO OR TWIN OR DOUBLE OR SECOND OR BOTH OR PAIR OR 2ND
S14   1349771   PLURAL???? OR SEVERAL OR MULTITUDE OR MULTIPLE OR MULTI OR
            MANY OR ADDITIONAL OR NUMEROUS OR SPARE OR EXTRA OR MORE()THA-
            T()ONE
S15   3255790   METHOD? ?
S16   7868408   SYSTEM? ?
S17    555254   PROCESS??
S18    325111   PROCEDURE? ?
S19   2050320   TECHNIQUE? ?
S20         8   S1:S5 AND S6 AND S7:S8 AND S9:S10 AND S11 AND S12 AND S13:-
            S14 AND S15:S19
S21         2   S20 AND PY<1999
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File   5:Biosis Previews(R) 1969-2004/Mar W1
         (c) 2004 BIOSIS
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Set     Items   Description
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             ACK()BONE? ?
S2     922067   BLOCK? ? OR BONEBLOCK? ? OR CHOCK? ? OR WEDGE? ? OR IMPLAN-
             T? ? OR INSERT? ? OR DOWEL? ? OR SPRAG? ? OR SWAGE? ? OR SHIM?
              ? OR SPACER? ? OR SPACING()ELEMENT? ?
S3    5641262   INSERT???? OR EMPLAC????? OR ADVANC????? OR INTRODUC????? -
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             IT??? OR DISPLAC??? OR DECOUPL??? OR DISJOIN??? OR DISCONNECT-
             ???
S6     104248   PARTITION??? OR SEGREGAT??? OR (CAM OR CAMS OR CAMMED OR C-
             AMMING OR SPREAD??? OR URGE? ? OR URGING)()APART
S7    2898013   ROTAT???? OR TWIRL??? OR TURN??? OR SPIN???? OR REVOLV??? -
             OR SCREW??? OR CIRCUMVOLV??? OR ORIENTAT???? OR GYRAT????
S8    1185560   REMOV???? OR WITHDRAW??? OR DISLODG??? OR EXTIRPAT???? OR -
             EVACUAT???? OR (TAKE? ? OR TAKING OR TOOK)()AWAY
S9   11547957   TWO OR TWIN OR DOUBLE OR SECOND OR BOTH OR PAIR OR 2ND
S10   9904855   PLURAL???? OR SEVERAL OR MULTITUDE OR MULTIPLE OR MULTI OR
             MANY OR ADDITIONAL OR NUMEROUS OR SPARE OR EXTRA OR MORE()THA-
             T()ONE
S11   1354967   METHOD? ?
S12   8195058   SYSTEM? ?
S13   3970002   PROCESS??
S14   1592938   PROCEDURE? ?
S15   1002400   TECHNIQUE? ?
S16        58   S1(5N)S2 AND S3:S4 AND S5:S6 AND S7 AND S8 AND S9:S10(5N)S-
               2:S4 AND S11:S15
S17        30   S16 AND PY<1999
S18        26   RD (unique items)
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File  16:Gale Group PROMT(R) 1990-2004/Mar 11
         (c) 2004 The Gale Group
File 160:Gale Group PROMT(R) 1972-1989
         (c) 1999 The Gale Group
File 148:Gale Group Trade & Industry DB 1976-2004/Mar 05
         (c)2004 The Gale Group
File 149:TGG Health&Wellness DB(SM) 1976-2004/Feb W5
         (c) 2004 The Gale Group
File 621:Gale Group New Prod.Annou.(R) 1985-2004/Mar 11
         (c) 2004 The Gale Group
File 444:New England Journal of Med. 1985-2004/Mar W2
         (c) 2004 Mass. Med.. Soc.
File 441:ESPICOM Pharm&Med DEVICE NEWS 2004/Mar W1
         (c) 2004 ESPICOM Bus.Intell.
File 369:New Scientist 1994-2004/Mar W1
         (c) 2004 Reed Business Information Ltd.
File 370:Science 1996-1999/Jul W3
         (c) 1999 AAAS
File 129:PHIND(Archival) 1980-2004/Mar W1
         (c) 2004 PJB Publications, Ltd.
File 130:PHIND(Daily & Current) 2004/Mar 12
         (c) 2004 PJB Publications,Ltd.
File 135:NewsRx Weekly Reports 1995-2004/Feb W5
         (c) 2004 NewsRx
File  98:General Sci Abs/Full-Text 1984-2004/Feb
         (c) 2004 The HW Wilson Co.
File  15:ABI/Inform(R) 1971-2004/Mar 12
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Set      Items   Description
S1          37   AU=(MCKINLEY J? OR MCKINLEY, J?)
S2         138   AU=(MARINO J? OR MARINO, J?)
S3         132   AU=(STONE C? OR STONE, C?)
S4        8497   (VERTEBR??? OR INTERVERTEBR???)
S5          59   (BONEBLOCK? ? OR BONE()BLOCK? ?)
S6      237714   IC=A61B?
S7          19   S1:S3 AND S4
S8          60   S1:S3 AND S6
S9           1   S8 AND S4 AND S5
S10         13   S8 AND S4:S5
S11         19   S7 OR S9 OR S10
? show files
File 347:JAPIO Nov 1976-2003/Nov(Updated 040308)
         (c) 2004 JPO & JAPIO
File 350:Derwent WPIX 1963-2004/UD,UM &UP=200416
         (c) 2004  THOMSON DERWENT
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11/3,K/5 (Item 5 from file: 350)
DIALOG(R)File 350:Derwent WPIX

014003864 **Image available**
WPI Acc No: 2001-488078/200153
Related WPI Acc No: 2000-053368; 2000-053403; 2000-062577; 2000-161234; 2000-256314; 2000-465601; 2000-465647; 2000-475594; 2000-543652; 2000-656406; 2000-665184; 2000-665185; 2000-665186; 2001-327217; 2001-637816; 2002-214238; 2002-214496; 2003-328171; 2003-370594
XRPX Acc No: N01-361156
Method of interlocking, first and second inserts between adjacent vertebrae **, by rotating the first insert to anchor it in position** between **the** vertebrae **, then introducing the second one and rotating it**
Patent Assignee: NUVASIVE INC (NUVA-N)
Inventor: AHLGREN D K; **MARINO J F**
Number of Countries: 001 Number of Patents: 001
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
US 6251140	B1	20010626	US 9886945	P	19980527	200153 B
			US 98113651	P	19981223	
			US 99120663	P	19990219	
			US 99320236	A	19990526	

Priority Applications (No Type Date): US 99320236 A 19990526; US 9886945 P 19980527; US 98113651 P 19981223; US 99120663 P 19990219
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
US 6251140	B1		14	A61F-002/44	Provisional application US 9886945
					Provisional application US 98113651
					Provisional application US 99120663

Method of interlocking, first and second inserts between adjacent vertebrae **, by rotating the first insert to anchor it in position between the** vertebrae **, then introducing the second one and rotating it**
...Inventor: **MARINO J F**

Abstract (Basic):
... The method of interlocking first and second inserts (20,30) between adjacent **vertebrae** (50,52) comprises introducing the first insert between adjacent **vertebrae** ; rotating the first insert to anchor the first insert into a fixed position between the adjacent **vertebrae** ; introducing the second insert between the adjacent **vertebrae** ; rotating the second insert to anchor the second insert into a fixed position between the adjacent **vertebrae** ; and fastening the first insert to the second insert.
... The first and second **vertebral** inserts are separately introduced into the inter **vertebral** space between the adjacent **vertebrae** by percutaneously introduced cannulae, each cannula being positioned in a postero-lateral approach. The central longitudinally extending axes of the first and second inter **vertebral** inserts are positioned to be angled from 70 - 135 degrees from one another. The inserts...

...In spinal surgery, in cases where the patient's **vertebral** discs have degenerated, e.g. by ageing or trauma...

...The figures show an exploded front perspective view of the first and second interlocking **intervertebral** inserts, and a side elevation of the inserts...

...adjacent **vertebrae** (50,52...
...Title Terms: **VERTEBRA** ;

11/3,K/6 (Item 6 from file: 350)
DIALOG(R)File 350:Derwent WPIX

013897266 **Image available**
WPI Acc No: 2001-381479/200140
XRPX Acc No: N01-279737

Inter- vertebral **support assembly, comprises pair of bone allografts positioned between two adjacent** vertebrae **, bone allografts being positioned towards anterior portion of adjacent** vertebrae **; and pair of facet screws**

Patent Assignee: NUVASIVE INC (NUVA-N)
Inventor: AHLGREN D; CORNWALL B; **MARINO J F** ; WOOLEY T; CORWALL B
Number of Countries: 093 Number of Patents: 003
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
WO 200141681	A1	20010614	WO 2000US33600	A	20001211	200140	B
AU 200127267	A	20010618	AU 200127267	A	20001211	200161	
US 6485518	B1	20021126	US 99172849	P	19991210	200281	
			US 2000735276	A	20001211		

Priority Applications (No Type Date): US 99172849 P 19991210; US 2000735276 A 20001211
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 200141681	A1	E	24	A61F-002/44	

Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY CA CH CN CR CU CZ DE DK DM DZ EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG UZ VN YU ZA ZW
Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW MZ NL OA PT SD SE SL SZ TR TZ UG ZW

AU 200127267	A		A61F-002/44	Based on patent WO 200141681
US 6485518	B1		A61F-002/44	Provisional application US 99172849

Inter- vertebral **support assembly, comprises pair of bone allografts positioned between two adjacent** vertebrae **, bone allografts being positioned towards anterior portion of adjacent** vertebrae **; and pair of facet screws**
...Inventor: **MARINO J F**

Abstract (Basic):
... The assembly comprises a pair of bone allografts (40A,40B) positioned between two adjacent **vertebrae** , the bone allografts being positioned towards the anterior portion of the adjacent **vertebrae** ; and a pair of facet screws (30A,30B), each facet screw securing together a facet joint between the two adjacent **vertebrae** . The bone allographs are positioned at an angle to one another. The bone allographs may...
... INDEPENDENT CLAIMS are included for a method for providing support between two adjacent **vertebrae** .
...

...Facilitates natural bone fusion between adjacent **vertebrae** . Allographs will eventually be resorbed into the patient's body as bone growth between immobilized **vertebrae** progresses
...Title Terms: **VERTEBRA** ;
International Patent Class (Additional): **A61B-017/70** ...

11/3,K/11 (Item 11 from file: 350)
DIALOG(R)File 350:Derwent WPIX

013484463 **Image available**
WPI Acc No: 2000-656406/200063
Related WPI Acc No: 2000-053368; 2000-053403; 2000-062577; 2000-161234; 2000-256314; 2000-465601; 2000-465647; 2000-475594; 2000-543652; 2000-665184; 2000-665185; 2000-665186; 2001-327217; 2001-488078; 2001-637816; 2002-214238; 2002-214496; 2003-328171; 2003-370594
XRPX Acc No: N00-486601

Segmented link intervertebral **implant system for promoting arthrodesis has elongated component dimensioned to pass through holes** of intervertebral **implants**

Patent Assignee: NUVASIVE INC (NUVA-N)
Inventor: **MARINO J F ; STONE C W**
Number of Countries: 092 Number of Patents: 003
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
WO 200062719	A1	20001026	WO 2000US9930	A	20000414	200063	B
AU 200042387	A	20001102	AU 200042387	A	20000414	200107	
US 6387130	B1	20020514	US 99129703	P	19990416	200239	
			US 2000549779	A	20000414		

Priority Applications (No Type Date): US 99129703 P 19990416; US 2000549779 A 20000414
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 200062719	A1	E	24	A61F-002/44	

Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY CA CH CN CR CU CZ DE DK DM DZ EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG UZ VN YU ZA ZW
Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW NL OA PT SD SE SL SZ TZ UG ZW

AU 200042387	A		Based on patent WO 200062719
US 6387130	B1	A61F-002/44	Provisional application US 99129703

Segmented link intervertebral **implant system for promoting arthrodesis has elongated component dimensioned to pass through holes of** intervertebral **implants**
Inventor: **MARINO J F** ...

... **STONE C W**

Abstract (Basic):

... **Intervertebral** implants (20A-20C), individually provided with a hole, are positioned in a patient's **intervertebral** space. An elongated component (30), such as wire, string, cord, tether, or suture, is dimensioned to pass through the hole of each **intervertebral** implant to hold together the **intervertebral** implants.

... An INDEPENDENT CLAIM is also included for a method for positioning **intervertebral** implants in **intervertebral** space of patient...

...Ensures easy positioning of **intervertebral** implants between two **vertebral** end plates around the curved periphery of the patient's **intervertebral** space. Degree of curvature of exhibited by C-shped assembly can be selected by selecting...

...placement of load supporting implant assembly over a large area between two of patient's **vertebrae** . Suitable for introduction to patient with minimally invasive surgical procedure. Attains reduction of required amount of **vertebral** distraction and tissue dissection, thus surgical time, complexity and trauma to patient are also reduced...

...The figure shows a diagram showing the method of placement of the **intervertebral** implants...
... **Intervertebral** implants (20A-20C
...Title Terms: **INTERVERTEBRAL** ;

11/3,K/12 (Item 12 from file: 350)
DIALOG(R)File 350:Derwent WPIX

013371713 **Image available**
WPI Acc No: 2000-543652/200049
Related WPI Acc No: 2000-053368; 2000-053403; 2000-062577; 2000-161234; 2000-256314; 2000-465601; 2000-465647; 2000-475594; 2000-656406; 2000-665184; 2000-665185; 2000-665186; 2001-327217; 2001-488078; 2001-637816; 2002-214238; 2002-214496; 2003-328171; 2003-370594
XRPX Acc No: N00-402131

Surgical access portal providing method for spinal surgery, involves advancing fastening element through cannula of obturator to reach patient's ilium, advancing bone cutting drill and drilling hole in ilium

Patent Assignee: NUVASIVE INC (NUVA-N)
Inventor: **MARINO J F**
Number of Countries: 086 Number of Patents: 004
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
WO 200048521	A1	20000824	WO 99US12610	A	19990604	200049	B
AU 9945479	A	20000904	AU 9945479	A	19990604	200103	
EP 1113756	A1	20010711	EP 99928407	A	19990604	200140	
			WO 99US12610	A	19990604		
JP 2002537014	W	20021105	WO 99US12610	A	19990604	200304	
			JP 2000599316	A	19990604		

Priority Applications (No Type Date): US 99129703 P 19990416; US 9888663 P 19980609; US 99120663 P 19990219
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 200048521	A1	E	24	A61B-017/56	
Designated States (National): AE AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG UZ VN YU ZA ZW					
Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW NL OA PT SD SE SL SZ UG ZW					
AU 9945479	A				Based on patent WO 200048521
EP 1113756	A1	E		A61B-017/56	Based on patent WO 200048521
Designated States (Regional): AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE					
JP 2002537014	W		25	A61B-017/56	Based on patent WO 200048521

Inventor: **MARINO J F**

Abstract (Basic):
... For drilling access portal through the ilium of patient for accessing patient's **intervertebral** space during spinal surgery...
...The method creates an access portal through the patient's ilium and **intervertebral** space preferably at a posterolateral angle, thereby being at the optimal angle of approach to the **intervertebral** space for the lower L5/S1 **vertebrae** . The bone cutter is adapted to provide for conveyance and deposition of wax into bone...
International Patent Class (Main): **A61B-017/56**

11/3,K/17 (Item 17 from file: 350)
DIALOG(R)File 350:Derwent WPIX

012890743 **Image available**
WPI Acc No: 2000-062577/200005
Related WPI Acc No: 2000-053368; 2000-053403; 2000-161234; 2000-256314; 2000-465601; 2000-465647; 2000-475594; 2000-543652; 2000-656406; 2000-665184; 2000-665185; 2000-665186; 2001-327217; 2001-488078; 2001-637816; 2002-214238; 2002-214496; 2003-328171; 2003-370594
XRAM Acc No: C00-017391
XRPX Acc No: N00-049002
Separating and stabilizing adjacent vertebrae **used in** intervertebral **discs degeneration**
Patent Assignee: NUVASIVE INC (NUVA-N)
Inventor: **MARINO J F**
Number of Countries: 083 Number of Patents: 002
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 9960957	A1	19991202	WO 99US11686	A	19990526	200005 B
AU 9944080	A	19991213	AU 9944080	A	19990526	200020

Priority Applications (No Type Date): US 99120663 P 19990219; US 9886945 P 19980527; US 98113651 P 19981223
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 9960957	A1	E	79	A61F-002/44	

Designated States (National): AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG UZ VN YU ZW
Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW NL OA PT SD SE SL SZ UG ZW

AU 9944080	A				Based on patent WO 9960957

Separating and stabilizing adjacent vertebrae **used in** intervertebral **discs degeneration**
Inventor: **MARINO J F**

Abstract (Basic):
... A method for separating and stabilizing adjacent **vertebrae** comprises rotating a first insert between the **vertebrae** to engage cam surfaces against the **vertebrae** and move them apart.
... An INDEPENDENT CLAIM is included for (A) an **intervertebral** insert which comprises a body having an anterior end, a posterior end, a rotational axis...
...disposed parallel to the rotational axis and which are adapted to engage and separate opposed **vertebral** surfaces when the insert is placed between adjacent **vertebrae** and rotated...

...The invention is used for separating and stabilizing adjacent **vertebrae** used in **intervertebral** discs degeneration...

...Camming the **vertebrae** apart with such outwardly facing convexly curved camming surfaces, minimized the side-to-side **vertebral** motion and the adjacent **vertebrae** do not tend to move horizontally with respect to one another, as they are cammed apart in a vertical direction. Minimal damage is done to the surface of the **vertebrae** because the contact between the sharp edges on the insert and the **vertebrae** is avoided. Rotation of the insert pushes apart the adjacent **vertebrae** without

tending to cause the adjacent **vertebrae** to move side-to-side with respect to one another...

...The figure shows an exploded perspective view of a pair of inserts positioned between adjacent **vertebrae** .

...

... **Vertebral** supporting surfaces (32a, 36a...
... **Vertebrae** (50, 52
Technology Focus:
... Preferred Methods: The method further comprises anchoring the insert between the **vertebrae** . The insert is inserted percutaneously. The percutaneous insertion comprises introducing a cannula and the insert. The method also comprises introducing a second insert between the **vertebrae** , the second insert is laterally spaced apart from the first insert; and rotating the second insert to support separation of the adjacent **vertebrae** . The first and second insert is anchored between the **vertebrae** . The anchoring comprises embedding penetrating elements on the insert into opposed surfaces of the adjacent **vertebrae** . The first and second insert are oriented at an angle (70-135 degrees) to one...

...axis and rotating the insert such that cam surfaces of the insert separate the adjacent **vertebrae** . In rotating the insert, the opposite flat surfaces disposed at opposite ends of the long axis buttress against the adjacent **vertebrae** . A coring device is introduced through a cannula. An elongated member connected to the insert...

...approach through a patient's back; introducing the insert through the cannula(e) into an **intervertebral** space between the two adjacent **vertebrate** ; and introducing an instrument through the second cannula into an **intervertebral** space between the two adjacent **vertebrae** . The posterolateral approach is at an angle of 35-90 degrees to an anterior-posterior...

...racetrack-shaped. The insert tapers to a narrow posterior end. The insert has opposite flat **vertebral** support surfaces disposed at a lordotic angle to one another. The opposite flat surfaces have...

...insert has a width which is 1.5-3 times greater than its height. The **intervertebral** insert further comprises a fenestration passing through the insert in a direction parallel or perpendicular...

...The insert is made of bio-absorbable material. The instrument is camera, arthroscope, articulate forceps, **vertebral** decorticator, shaver, osteophyte file, and bone graft introducer...
...Title Terms: **VERTEBRA** ;

11/3,K/18 (Item 18 from file: 350)
DIALOG(R)File 350:Derwent WPIX

012881569 **Image available**
WPI Acc No: 2000-053403/200004
Related WPI Acc No: 2000-053368; 2000-062577; 2000-161234; 2000-256314; 2000-465601; 2000-465647; 2000-475594; 2000-543652; 2000-656406; 2000-665184; 2000-665185; 2000-665186; 2001-327217; 2001-488078; 2001-637816; 2002-214238; 2002-214496; 2003-328171; 2003-370594
XRPX Acc No: N00-041570
Intervertebral **spinal inserts interlocking method for patients undergoing major surgery**
Patent Assignee: NUVASIVE INC (NUVA-N)
Inventor: AHLGREN D K; **MARINO J F**
Number of Countries: 083 Number of Patents: 002
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
WO 9960956	A1	19991202	WO 99US11593	A	19990526	200004	B
AU 9940995	A	19991213	AU 9940995	A	19990526	200020	

Priority Applications (No Type Date): US 99120663 P 19990219; US 9886945 P 19980527; US 98113651 P 19981223
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 9960956	A1	E	25	A61F-002/44	

Designated States (National): AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG UZ VN YU ZW
Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW NL OA PT SD SE SL SZ UG ZW

AU 9940995	A			Based on patent WO 9960956

Intervertebral **spinal inserts interlocking method for patents undergoing major surgery**
...Inventor: **MARINO J F**

Abstract (Basic):
... The insert (20) is introduced between adjacent **vertebrae** (50,52) and rotated to anchor insert (20) into a fixed position. Another insert (30) is introduced between the adjacent **vertebrae** , rotated to anchor insert (30) into a fixed position and the insert (20) is fastened...
... For inserting spinal inserts and interlocking between adjacent **vertebrae** in cases where patient's **vertebral** discs are degenerated during major surgery...

...central longitudinally extending axes of the inserts are oriented generally perpendicular to each other, increased **vertebrae** stability is provided, and the potential for **vertebral** fusion is increased. The inserts are interlocked together with one another enhancing their stability...

...The figure shows an exploded front perspective view of two interlocking **intervertebral** inserts interlocked together and anchored into a position between the **vertebrae** .
...

...Adjacent **vertebrae** (50,52

Title Terms: **INTERVERTEBRAL** ;
International Patent Class (Additional): **A61B-017/56**

11/3,K/19 (Item 19 from file: 350)
DIALOG(R)File 350:Derwent WPIX

012881534 **Image available**
WPI Acc No: 2000-053368/200004
Related WPI Acc No: 2000-053403; 2000-062577; 2000-161234; 2000-256314; 2000-465601; 2000-465647; 2000-475594; 2000-543652; 2000-656406; 2000-665184; 2000-665185; 2000-665186; 2001-327217; 2001-488078; 2001-637816; 2002-214238; 2002-214496; 2003-328171; 2003-370594
XRPX Acc No: N00-041539
Bone blocks **inserting method into patient's** intervertebral **space**
Patent Assignee: NUVASIVE INC (NUVA-N)
Inventor: **MARINO J F** ; **MCKINLEY J T** ; **STONE C W** ; MARINO M J F; **MCKINLEY J K**
Number of Countries: 084 Number of Patents: 008
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
WO 9960837	A2	19991202	WO 99US11597	A	19990526	200004	B
AU 9942058	A	19991213	AU 9942058	A	19990526	200020	
US 6290724	B1	20010918	US 9886945	P	19980527	200157	
			US 98113651	P	19981223		
			US 99120663	P	19990219		
			US 99320161	A	19990526		
US 6312443	B1	20011106	US 98113651	P	19981223	200170	
			US 99467944	A	19991221		
KR 2001071658	A	20010731	KR 2000713959	A	20001208	200208	
US 6368325	B1	20020409	US 9886945	P	19980527	200227	
			US 98113651	P	19981223		
			US 99120663	P	19990219		
			US 99320081	A	19990526		
US 20020055745	A1	20020509	US 9886945	P	19980527	200235	
			US 98113651	P	19981223		
			US 99120663	P	19990219		
			US 99320081	A	19990526		
			US 200132121	A	20011221		
JP 2002529117	W	20020910	WO 99US12609	A	19990604	200274	
			JP 2000565788	A	19990604		

Priority Applications (No Type Date): US 99120663 P 19990219; US 9886945 P 19980527; US 98113651 P 19981223; US 99320161 A 19990526; US 99467944 A 19991221; US 9888863 A 19980609; US 99326740 A 19990604; US 99320081 A 19990526; US 200132121 A 20011221; US 9888663 P 19980609
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 9960837	A2	E	60	A61F-000/00	
Designated States (National): AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG UZ VN YU ZW					
Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW NL OA PT SD SE SL SZ UG ZW					
AU 9942058	A				Based on patent WO 9960837
US 6290724	B1			A61F-002/44	Provisional application US 9886945
					Provisional application US 98113651
					Provisional application US 99120663
US 6312443	B1			A61M-029/00	Provisional application US 98113651
KR 2001071658	A			A61B-006/08	
US 6368325	B1			A61F-002/46	Provisional application US 9886945
					Provisional application US 98113651
					Provisional application US 99120663

US 20020055745 A1 A61B-017/88 Provisional application US 9886945

Provisional application US 98113651
Provisional application US 99120663
Cont of application US 99320081
JP 2002529117 W 17 A61B-006/00 Based on patent WO 200010461

Bone blocks **inserting method into patient's** intervertebral **space**
Inventor: **MARINO J F** ...

... **MCKINLEY J T** ...

... **STONE C W** ...

... **MCKINLEY J K**

Abstract (Basic):
... The **bone block** (10b) is supported in an inserter (20) which is advanced into the **intervertebral** space. After the inserter is received into the patient's **intervertebral** space, it is rotated approximately ninety degrees. Convexly curved outer camming surfaces on the inserter operate to separate the adjacent **vertebral** as the inserter is rotated.
... Rotation of the inserter by ninety degrees also operates to orient the **bone block** in a preferred orientation relative to the opposite **vertebral** surfaces. An INDEPENDENT CLAIM is also included for a system for introducing a **bone block** into the **intervertebral** space of a patient...

...For inserting a **bone block** into patient's **intervertebral** space...
...After the **bone block** is rotated into position, it supports the spinal load, thereby easing pressure on the **vertebral** disc and surrounding tissue. As such prior distraction of the adjacent **vertebrae** with dedicated instrumentation is substantially minimized. After the **bone block** is rotated into an anchored position between the adjacent **vertebrae** , the inserter is withdrawn from the **intervertebral** space leaving the **bone block** in a preferred position to promote bone fusion between the adjacent **vertebrae** .
...

...The figure shows the perspective view of **bone block** inserter...

... **Bone block** (10b
...Title Terms: **INTERVERTEBRAL** ;
International Patent Class (Main): **A61B-006/00** ...

... **A61B-006/08** ...

... **A61B-017/88**

```
Set     Items   Description
S1         25   AU=(MCKINLEY J? OR MCKINLEY, J?)
S2        106   AU=(MARINO J? OR MARINO, J?)
S3         96   AU=(STONE C? OR STONE, C?)
S4      18634   (VERTEBR??? OR INTERVERTEBR???)
S5        117   (BONEBLOCK? ? OR BONE()BLOCK? ?)
S6      51674   IC=A61B?
S7         24   S1:S3 AND S4
S8         62   S1:S3 AND S6
S9          0   S8 AND S5
S10        14   S8 AND S4:S5
S11        24   S7 OR S10
? show files
File 348:EUROPEAN PATENTS 1978-2004/Feb W05
         (c) 2004 European Patent Office
File 349:PCT FULLTEXT 1979-2002/UB=20040304,UT=20040226
         (c) 2004 WIPO/Univentio
```

11/5,AU/1 (Item 1 from file: 348)
DIALOG(R)File 348:EUROPEAN PATENTS

01312667
FACET SCREW AND BONE ALLOGRAFT INTERVERTEBRAL **SUPPORT AND FUSION SYSTEM**
VIS A FACETTE ET SYSTEME DE SUPPORT ET DE FUSION INTERVERTEBRAUX **AVEC ALLOGREFFES OSSEUSES**
PATENT ASSIGNEE:
Nuvasive Inc., (2900090), 10065 Old Grove Road, San Diego, CA 92131, (US)
, (Applicant designated States: all)
INVENTOR:
CORWALL, Bryan, 10675 Tipperary Way, San Diego, CA 92131, (US)
MARINO, James, F. , 2620 St. Tropez Place, La Jolla, CA 92037, (US)
AHLGREN, Dan, 17446 Matinal Road, 4812, San Diego, CA 92127, (US)
WOOLEY, Troy, 1457 Reed Avenue, San Diego, CA 92109, (US
PATENT (CC, No, Kind, Date):
WO 2001041681 010614
APPLICATION (CC, No, Date): EP 2000990207 001211; WO 2000US33600 001211
PRIORITY (CC, No, Date): US 172849 P 991210
DESIGNATED STATES: AT; BE; CH; CY; DE; DK; ES; FI; FR; GB; GR; IE; IT; LI; LU; MC; NL; PT; SE; TR
EXTENDED DESIGNATED STATES: AL; LT; LV; MK; RO; SI
INTERNATIONAL PATENT CLASS: A61F-002/44; A61F-005/00
CITED PATENTS (WO A): US 6045580 A
LEGAL STATUS (Type, Pub Date, Kind, Text):
Application: 010808 A1 International application. (Art. 158(1))
Application: 010808 A1 International application entering European phase
Application: 030122 A1 International application. (Art. 158(1))
Appl Changed: 030122 A1 International application not entering European phase
Withdrawal: 030122 A1 Date application deemed withdrawn: 20020711
LANGUAGE (Publication,Procedural,Application): English; English; English

11/5,AU/2 **(Item 2 from file: 348)**
DIALOG(R)File 348:EUROPEAN PATENTS

01224104
SEGMENTED LINKED INTERVERTEBRAL **IMPLANT SYSTEMS**
SYSTEMES D'IMPLANTS INTERVERTEBRAUX **INDIVIDUELS RELIES ENTRE EUX**
PATENT ASSIGNEE:
Nuvasive Inc., (2900090), 10065 Old Grove Road, San Diego, CA 92131, (US)
, (Applicant designated States: all)
INVENTOR:
STONE, Corbett, W. , 12212 Misty Blue Court, San Diego, CA 92131, (US)
MARINO, James, F. , 2620 St. Tropez Place, La Jolla, CA 92307, (US
PATENT (CC, No, Kind, Date): WO 2000062719 001026
APPLICATION (CC, No, Date): EP 2000922158 000414; WO 2000US9930 000414
PRIORITY (CC, No, Date): US 129703 P 990416
DESIGNATED STATES: AT; BE; CH; CY; DE; DK; ES; FI; FR; GB; GR; IE; IT; LI; LU; MC; NL; PT; SE
INTERNATIONAL PATENT CLASS: A61F-002/44
CITED PATENTS (WO A): US 5192327 A ; US 5217497 A ; US 5755797 A
LEGAL STATUS (Type, Pub Date, Kind, Text):

Application:	001220	A1 International application. (Art. 158(1))
Application:	001220	A1 International application entering European phase
Application:	021113	A1 International application. (Art. 158(1))
Appl Changed:	021113	A1 International application not entering European phase
Withdrawal:	021113	A1 Date application deemed withdrawn: 20011117

LANGUAGE (Publication,Procedural,Application): English; English; English

11/5,AU/3 **(Item 3 from file: 348)**
DIALOG(R)File 348:EUROPEAN PATENTS

01202759
TRANSILIAC APPROACH TO ENTERING A PATIENT'S INTERVERTEBRAL **SPACE**
TRANSILIAKALE ZUGANGSMETHODE FUR DEN ZWISCHENWIRBELRAUM
APPROCHE TRANSILIAQUE POUR ACCEDER A L'ESPACE INTERVERTEBRAL **D'UN SUJET**
PATENT ASSIGNEE:
Nuvasive Inc., (2900090), 10065 Old Grove Road, San Diego, CA 92131, (US)
, (Applicant designated States: all)
INVENTOR:
MARINO, James, F. , 2620 St. Tropez Place, La Jolla, CA 92037, (US
LEGAL REPRESENTATIVE:
Merrifield, Sarah Elizabeth et al (84691), Boult Wade Tennant Verulam Gardens 70 Gray's Inn Road, London WC1X 8BT, (GB)
PATENT (CC, No, Kind, Date): EP 1113756 A1 010711 (Basic)
WO 200048521 000824
APPLICATION (CC, No, Date): EP 99928407 990604; WO 99US12610 990604
PRIORITY (CC, No, Date): US 88663 P 980609; US 120663 P 990219; US 129703 P 990416
DESIGNATED STATES: AT; BE; CH; CY; DE; DK; ES; FI; FR; GB; GR; IE; IT; LI; LU; MC; NL; PT; SE
INTERNATIONAL PATENT CLASS: **A61B-017/56**
CITED PATENTS (WO A): US 5484437 A ; US 5632747 A ; US 5899908 A
NOTE:
No A-document published by EPO
LEGAL STATUS (Type, Pub Date, Kind, Text):
Application: 001018 A1 International application. (Art. 158(1))
Application: 001018 A1 International application entering European phase
Application: 010711 A1 Published application with search report
Examination: 010711 A1 Date of request for examination: 20010108
Priority: 010808 A1 Priority information changed: 20010620
Withdrawal: 030709 A1 Date application deemed withdrawn: 20030103
LANGUAGE (Publication,Procedural,Application): English; English; English

11/5,AU/6 (Item 6 from file: 348)
DIALOG(R)File 348:EUROPEAN PATENTS

01116671
METHODS AND APPARATUS FOR SEPARATING AND STABILIZING ADJACENT VERTEBRAE
PROCEDES ET APPAREIL PERMETTANT DE SEPARER ET DE STABILISER DES VERTEBRES **ADJACENTES**
PATENT ASSIGNEE:
Nuvasive Inc., (2900090), 10065 Old Grove Road, San Diego, CA 92131, (US) , (Applicant designated States: all)
INVENTOR:
MARINO, James, F. , 2620 St. Tropez Street, La Jolla, CA 92307, (US
PATENT (CC, No, Kind, Date):
WO 9960957 991202
APPLICATION (CC, No, Date): EP 99927097 990526; WO 99US11686 990526
PRIORITY (CC, No, Date): US 86945 P 980527; US 113651 P 981223; US 120663 P 990219
DESIGNATED STATES: AT; BE; CH; CY; DE; DK; ES; FI; FR; GB; GR; IE; IT; LI; LU; MC; NL; PT; SE
INTERNATIONAL PATENT CLASS: A61F-002/44
LEGAL STATUS (Type, Pub Date, Kind, Text):
Application: 011024 A1 International application. (Art. 158(1))
Application: 20000202 A1 International application. (Art. 158(1))
Withdrawal: 011024 A1 Date application deemed withdrawn: 20001228
Appl Changed: 011024 A1 International application not entering European phase
Application: 20000202 A1 International application entering European phase
LANGUAGE (Publication,Procedural,Application): English; English; English

11/5,AU/7 (Item 7 from file: 348)
DIALOG(R)File 348:EUROPEAN PATENTS

01114130
BONE BLOCKS AND METHODS FOR INSERTING BONE BLOCKS INTO INTERVERTEBRAL **SPACES**
BUTEES OSSEUSES ET INSERTION DE BUTEES OSSEUSES DANS LES ESPACES INTERVERTEBRAUX
PATENT ASSIGNEE:
Nuvasive Inc., (2900090), 10065 Old Grove Road, San Diego, CA 92131, (US) , (Applicant designated States: all)
INVENTOR:
MCKINLEY, James, K. , 17560 Skyline Boulevard, Woodside, CA 94062, (US)
MARINO, MD., James, F., 2620 St. Tropez Street, La Jolla, CA 92307, (US)
STONE, Corbett, W. , 12212 Misty Blue Court, San Diego, CA 92131, (US
PATENT (CC, No, Kind, Date):
WO 9960837 991202
APPLICATION (CC, No, Date): EP 99925855 990526; WO 99US11597 990526
PRIORITY (CC, No, Date): US 86945 P 980527; US 113651 P 981223; US 120663 P 990219
DESIGNATED STATES: AT; BE; CH; CY; DE; DK; ES; FI; FR; GB; GR; IE; IT; LI; LU; MC; NL; PT; SE
INTERNATIONAL PATENT CLASS: A61F-002/44
LEGAL STATUS (Type, Pub Date, Kind, Text):

Application:	011024	A2 International application. (Art. 158(1))
Application:	20000126	A2 International application. (Art. 158(1))
Withdrawal:	011024	A2 Date application deemed withdrawn: 20001228
Appl Changed:	011024	A2 International application not entering European phase
Application:	20000126	A2 International application entering European phase

LANGUAGE (Publication,Procedural,Application): English; English; English

11/5,AU/10 (Item 3 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00808522
FACET SCREW AND BONE ALLOGRAFT INTERVERTEBRAL **SUPPORT AND FUSION SYSTEM**
VIS A FACETTE ET SYSTEME DE SUPPORT ET DE FUSION INTERVERTEBRAUX **AVEC ALLOGREFFES OSSEUSES**

Patent Applicant/Assignee:
NUVASIVE INC, 10065 Old Grove Road, San Diego, CA 92131, US, US (Residence), US (Nationality)
Inventor(s):
CORWALL Bryan, 10675 Tipperary Way, San Diego, CA 92131, US,
MARINO James F , 2620 St. Tropez Place, La Jolla, CA 92037, US,
AHLGREN Dan, 17446 Matinal Road, #4812, San Diego, CA 92127, US,
WOOLEY Troy, 1457 Reed Avenue, San Diego, CA 92109, US
Legal Representative:
HECKADON David R (et al) (agent), Townsend and Townsend and Crew LLP, Two Embarcadero Center, 8th floor, San Francisco, CA 94111-3834, US,
Patent and Priority Information (Country, Number, Date):
Patent: WO 200141681 A1 20010614 (WO 0141681)
Application: WO 2000US33600 20001211 (PCT/WO US0033600)
Priority Application: US 99172849 19991210
Designated States: AE AG AL AM AT AU AZ BA BB BG BR BY CA CH CN CR CU CZ DE DK DM DZ EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG UZ VN YU ZA ZW
(EP) AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE TR
(OA) BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG
(AP) GH GM KE LS MW MZ SD SL SZ TZ UG ZW
(EA) AM AZ BY KG KZ MD RU TJ TM
Main International Patent Class: A61F-002/44
International Patent Class: A61F-005/00
Publication Language: English
Filing Language: English
Fulltext Word Count: 4685

English Abstract
An intervertebral support assembly, comprising a pair of bone allografts (40A and 40B) positioned between two adjacent **vertebrae** , the bone allografts being positioned towards the anterior portion of the adjacent **vertebrae** ; and a pair of facet screws (30A and 30B), each facet screw securing together a facet joint between the two adjacent **vertebrae** . A method of providing support between two adjacent **vertebrae** , comprising positioning a pair of bone allografts (40A and 40B) between the two adjacent **vertebrae** at a location towards the front of the adjacent **vertebrae** ; and securing together facet joints between the two adjacent **vertebrae** with a pair of facet screws (30A and 30B).

French Abstract
L'invention concerne un ensemble de support **intervertebral** comprenant deux allogreffes (40A, 40B) osseuses placees entre deux **vertebres** adjacentes, ces allogreffes etant positionnees dans la region anterieure des **vertebres** adjacentes, et deux vis (30A, 30B) a facette, chaque vis servant a fixer ensemble les facettes articulaires comprises entre les deux **vertebres** adjacentes. L'invention concerne en outre un procede permettant d'inserer un support entre deux **vertebres** adjacentes. Ce procede consiste a positionner deux greffons (40A, 40B) allogeniques entre les deux **vertebres** adjacentes, dans un point situe dans la region frontale des **vertebres** adjacentes, et a fixer ensemble les facettes

articulaires comprises entre ces deux **vertebres** a l'aide de deux vis (30A, 30B) a facette.

Legal Status (Type, Date, Text)
Publication 20010614 A1 With international search report.
Publication 20010614 A1 Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.
Examination 20010913 Request for preliminary examination prior to end of 19th month from priority date

11/5,AU/14 (Item 7 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00749705
SEGMENTED LINKED INTERVERTEBRAL **IMPLANT SYSTEMS**
SYSTEMES D'IMPLANTS INTERVERTEBRAUX **INDIVIDUELS RELIES ENTRE EUX**
Patent Applicant/Assignee:
NUVASIVE INC, 10065 Old Grove Road, San Diego, CA 92131, US, US (Residence), US (Nationality)
Inventor(s):
STONE Corbett W , 12212 Misty Blue Court, San Diego, CA 92131, US
MARINO James F , 2620 St. Tropez Place, La Jolla, CA 92307, US
Legal Representative:
HECKADON David R, Townsend and Townsend and Crew LLP, Two Embarcadero Center, 8th floor, San Francisco, CA 94111-3834, US
Patent and Priority Information (Country, Number, Date):
Patent: WO 200062719 A1 20001026 (WO 0062719)
Application: WO 2000US9930 20000414 (PCT/WO US0009930)
Priority Application: US 99129703 19990416
Designated States: AE AG AL AM AT AU AZ BA BB BG BR BY CA CH CN CR CU CZ DE DK DM DZ EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG UZ VN YU ZA ZW
(EP) AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE
(OA) BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG
(AP) GH GM KE LS MW SD SL SZ TZ UG ZW
(EA) AM AZ BY KG KZ MD RU TJ TM
Main International Patent Class: A61F-002/44
Publication Language: English
Filing Language: English
Fulltext Word Count: 4231

English Abstract
This invention is a method of positioning a plurality of **intervertebral** implants (20) in a patient's **intervertebral** space, comprising introducing an elongated member (30) into the patient's **intervertebral** space; and sequentially advancing a plurality of **intervertebral** implants (20) over the elongated member (30), and into the patient's **intervertebral** space, the plurality of **intervertebral** implants (20) each having at least one hole (21) passing therethrough, with the elongated member (30) received through the holes (21) passing through each of the plurality of implants (20).

French Abstract
La presente invention concerne un procede de positionnement d'une pluralite d'implants **intervertebraux** (20) dans l'espace **intervertebral** d'un patient. Ce procede consiste a introduire un element allonge (30) dans l'espace **intervertebral** du patient et a faire avancer sequentiellement plusieurs implants **intervertebraux** (20) sur l'element allonge (30) puis a l'interieur de l'espace **intervertebral** ; chacun des implants **intervertebraux** comportant au moins un orifice (21) traversant, ledit element allonge (30) se logeant dans lesdits orifices (21) traversant chacun des implants (20).

Legal Status (Type, Date, Text)
Publication 20001026 A1 With international search report.
Examination 20010118 Request for preliminary examination prior to end of 19th month from priority date

11/5,AU/16 (Item 9 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00735518
TRANSILIAC APPROACH TO ENTERING A PATIENT'S INTERVERTEBRAL **SPACE**
APPROCHE TRANSILIAQUE POUR ACCEDER A L'ESPACE INTERVERTEBRAL **D'UN SUJET**
Patent Applicant/Assignee:
NUVASIVE INC, 10065 Old Grove Road, San Diego, CA 92131, US, US (Residence), US (Nationality)
Inventor(s):
MARINO James F , 2620 St. Tropez Place, La Jolla, CA 92037, US
Legal Representative:
HECKADON David R (et al) (agent), Townsend and Townsend and Crew LLP, 8th floor, Two Embarcadero Center, San Francisco, CA 94111, US,
Patent and Priority Information (Country, Number, Date):
Patent: WO 200048521 A1 20000824 (WO 0048521)
Application: WO 99US12610 19990604 (PCT/WO US9912610)
Priority Application: US 9888663 19980609; US 99120663 19990219; US 99129703 19990416
Designated States: AE AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG UZ VN YU ZA ZW
(EP) AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE
(OA) BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG
(AP) GH GM KE LS MW SD SL SZ UG ZW
(EA) AM AZ BY KG KZ MD RU TJ TM
Main International Patent Class: **A61B-017/56**
Publication Language: English
Filing Language: English
Fulltext Word Count: 3192

English Abstract
The present invention provides methods for percutaneously accessing the patient's **intervertebral** space (18) by creating an access portal (30) through the patient's ilium (16) and into the patient's **intervertebral** space (18). The access portal (30) created is preferably at a posterolateral angle, (preferably in the range of 40 to 90 degrees to an anterior/posterior axis through the patient), thereby being at the optimal angle of approach to the **intervertebral** space (18) for these lower L5/S1 **vertebrae** . Methods are also provided for advancing surgical instruments through the passage, and into the **intervertebral** space (18).

French Abstract
L'invention concerne des procedes permettant d'acceder par voie percutanee a l'espace **intervertebral** (18) d'un sujet en creant un orifice d'acces (30) traversant l'ilion (16) et penetrant dans l'espace **intervertebral** (18). Cet orifice d'acces (30) se situe de preference a un angle postero-lateral, (de preference dans une fourchette de 40 a 90 degres par rapport a un axe anterieur-posterieur traversant le sujet), ce qui constitue l'angle d'approche optimal de l'espace **intervertebral** (18) pour les **vertebres** inferieures L5/S1. L'invention concerne egalement des procedes permettant d'introduire, par le passage cree, des instruments chirurgicaux dans l'espace **intervertebral** (18).

Legal Status (Type, Date, Text)
Publication 20000824 A1 With international search report.
Examination 20000921 Request for preliminary examination prior to end of

		19th month from priority date
Correction	20010816	Corrections of entry in Section 1: under (30) add "60/088,663, 9 June 1998 (09.06.98), US"
Republication	20010816	A1 With international search report.

11/5,AU/23 **(Item 16 from file: 349)**
DIALOG(R)File 349:PCT FULLTEXT

00529604
INTERLOCKING SPINAL INSERTS
INTERBLOCAGE D'INSERTS RACHIDIENS
Patent Applicant/Assignee:
NUVASIVE INC,
Inventor(s):
MARINO James F ,
AHLGREN Daniel K
Patent and Priority Information (Country, Number, Date):
Patent: WO 9960956 A1 19991202
Application: WO 99US11593 19990526 (PCT/WO US9911593)
Priority Application: US 9886945 19980527; US 98113651 19981223; US 99120663 19990219
Designated States: AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG UZ VN YU ZW GH GM KE LS MW SD SL SZ UG ZW AM AZ BY KG KZ MD RU TJ TM AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG
Main International Patent Class: A61F-002/44
International Patent Class: **A61B-017/56**
Publication Language: English
Fulltext Word Count: 3705

English Abstract
A method of interlocking first (20) and second (30) inserts between adjacent **vertebrae** (50, 52) comprising: introducing the first insert (20) between adjacent **vertebrae** (50, 52); rotating the first insert to anchor the first insert (20) into a fixed position between the adjacent **vertebrae** (50, 52); introducing the second insert (30) between the adjacent **vertebrae** (50, 52); rotating the second insert (30) to anchor the second insert into a fixed position between the adjacent **vertebrae** (50, 52); and fastening the first insert (20) to the second insert (30).

French Abstract
La presente invention concerne un procede permettant l'interblocage d'un premier insert (20) avec un second insert (30) s'intercalant entre deux **vertebres** consecutives (50, 52). Ce procede consiste d'abord a presenter le premier insert (20) entre les deux **vertebres** consecutives (50, 52), puis le (20) faire tourner jusqu'a l'ancrer en position fixe entre les deux **vertebres** consecutives (50, 52). Le procede consiste ensuite a presenter le second insert (30) entre les deux **vertebres** consecutives (50, 52), puis le (30) faire tourner jusqu'a l'ancrer en position fixe entre les deux **vertebres** consecutives (50, 52). Le procede consiste enfin a fixer le premier insert (20) au second insert (30).

11/5,AU/24 (Item 17 from file: 349)
DIALOG(R)File 349:PCT FULLTEXT

00529485
BONE BLOCKS AND METHODS FOR INSERTING BONE BLOCKS INTO INTERVERTEBRAL **SPACES**
BUTEES OSSEUSES ET INSERTION DE BUTEES OSSEUSES DANS LES ESPACES INTERVERTEBRAUX
Patent Applicant/Assignee:
NUVASIVE INC,
Inventor(s):
MCKINLEY James K ,
MARINO MD James F,
STONE Corbett W
Patent and Priority Information (Country, Number, Date):
Patent: WO 9960837 A2 19991202
Application: WO 99US11597 19990526 (PCT/WO US9911597)
Priority Application: US 9886945 19980527; US 98113651 19981223; US 99120663 19990219
Designated States: AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG UZ VN YU ZW GH GM KE LS MW SD SL SZ UG ZW AM AZ BY KG KZ MD RU TJ TM AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG
Publication Language: English
Fulltext Word Count: 7040

English Abstract
A method for inserting a bone block into a patient's **intervertebral** space, comprising: supporting the bone block in an inserter; advancing the inserter into the **intervertebral** space; rotating the inserter, thereby separating adjacent **vertebrae** ; separating the bone block and the inserter with a push rod; and removing the inserter from the **intervertebral** space.

French Abstract
La presente invention concerne un procede servant a l'insertion de butees osseuses dans un espace **intervertebral** d'un patient. Ce procede consiste a placer la butee osseuse dans un introducteur puis a pousser l'introducteur dans l'espace **intervertebral** . Le procede consiste ensuite faire tourner l'introducteur, ce qui produit une separation des **vertebres** consecutives, puis a detacher de l'introducteur la butee osseuse au moyen d'une tige poussoir. Il ne reste plus qu'a retirer l'introducteur de l'espace **intervertebral** .

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Set     Items   Description
S1        779   AU=(MCKINLEY J? OR MCKINLEY, J?)
S2       1403   AU=(MARINO J? OR MARINO, J?)
S3       3041   AU=(STONE C? OR STONE, C?)
S4   12132698   (VERTEBR??? OR INTERVERTEBR???)
S5       1212   (BONEBLOCK? ? OR BONE()BLOCK? ?)
S6        653   S1:S3 AND S4:S5
S7          1   S6 AND S4 AND S5
? show files
File 155:MEDLINE(R) 1966-2004/Mar W1
         (c) format only 2004 The Dialog Corp.
File   2:INSPEC 1969-2004/Feb W5
         (c) 2004 Institution of Electrical Engineers
File   5:Biosis Previews(R) 1969-2004/Mar W1
         (c) 2004 BIOSIS
File   6:NTIS 1964-2004/Mar W1
         (c) 2004 NTIS, Intl Cpyrght All Rights Res
File   8:Ei Compendex(R) 1970-2004/Feb W5
         (c) 2004 Elsevier Eng.  Info. Inc.
File  34:SciSearch(R) Cited Ref Sci 1990-2004/Mar W1
         (c) 2004 Inst for Sci Info
File 434:SciSearch(R) Cited Ref Sci 1974-1989/Dec
         (c) 1998 Inst for Sci Info
File  73:EMBASE 1974-2004/Mar W1
         (c) 2004 Elsevier Science B.V.
File  71:ELSEVIER BIOBASE 1994-2004/Feb W5
         (c) 2004  Elsevier Science B.V.
File 144:Pascal 1973-2004/Feb W5
         (c) 2004 INIST/CNRS
File  35:Dissertation Abs Online 1861-2004/Feb
         (c) 2004 ProQuest Info&Learning
File  65:Inside Conferences 1993-2004/Mar W1
         (c) 2004 BLDSC all rts. reserv.
File  94:JICST-EPlus 1985-2004/Feb W5
         (c)2004 Japan Science and Tech Corp(JST)
File  95:TEME-Technology & Management 1989-2004/Feb W4
         (c) 2004 FIZ TECHNIK
File  99:Wilson Appl. Sci & Tech Abs 1983-2004/Feb
         (c) 2004 The HW Wilson Co.
File 481:DELPHES Eur Bus 95-2004/Feb W5
         (c) 2004 ACFCI & Chambre CommInd Paris
File 583:Gale Group Globalbase(TM) 1986-2002/Dec 13
         (c) 2002 The Gale Group
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7/3,K/1 (Item 1 from file: 5)
DIALOG(R)File 5:Biosis Previews(R)

0013689115 BIOSIS NO.: 200200282626
Bone blocks **and methods for inserting** bone blocks **into** intervertebral **spaces**
AUTHOR: **McKinley James T** (Reprint); **Marino James F** ; **Stone Corbett W**
AUTHOR ADDRESS: Woodside, CA, USA**USA
JOURNAL: Official Gazette of the United States Patent and Trademark Office Patents 1257 (2): Apr. 9, 2002 2002
MEDIUM: e-file
PATENT NUMBER: US 6368325 PATENT DATE GRANTED: April 09, 2002 20020409
PATENT CLASSIFICATION: 606-99 PATENT ASSIGNEE: NuVasive, Inc.
PATENT COUNTRY: USA
ISSN: 0098-1133
DOCUMENT TYPE: Patent
RECORD TYPE: Abstract
LANGUAGE: English

Bone blocks **and methods for inserting** bone blocks **into** intervertebral **spaces**
AUTHOR: **McKinley James T** ...

... **Marino James F** ...
... **Stone Corbett W**

ABSTRACT: A method for inserting a **bone block** into a patient's **intervertebral** space, comprising: supporting the **bone block** in an inserter; advancing the inserter into the **intervertebral** space; rotating the inserter, thereby separating adjacent **vertebrae** ; separating the **bone block** and the inserter with a push rod; and removing the inserter from the **intervertebral** space.
DESCRIPTORS:
METHODS & EQUIPMENT: **bone blocks** --...

... **intervertebral** space **bone block** insertion method

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Set     Items   Description
S1        300   AU=(MCKINLEY J? OR MCKINLEY, J?)
S2        238   AU=(MARINO J? OR MARINO, J?)
S3        179   AU=(STONE C? OR STONE, C?)
S4      16993   (VERTEBR??? OR INTERVERTEBR???)
S5        185   (BONEBLOCK? ? OR BONE()BLOCK? ?)
S6          0   S1:S3 AND S4:S5
? show files
File  16:Gale Group PROMT(R) 1990-2004/Mar 11
         (c) 2004 The Gale Group
File 160:Gale Group PROMT(R) 1972-1989
         (c) 1999 The Gale Group
File 148:Gale Group Trade & Industry DB 1976-2004/Mar 05
         (c)2004 The Gale Group
File 149:TGG Health&Wellness DB(SM) 1976-2004/Feb W5
         (c) 2004 The Gale Group
File 621:Gale Group New Prod.Annou.(R) 1985-2004/Mar 11
         (c) 2004 The Gale Group
File 444:New England Journal of Med. 1985-2004/Mar W2
         (c) 2004 Mass. Med. Soc.
File 441:ESPICOM Pharm&Med DEVICE NEWS 2004/Mar W1
         (c) 2004 ESPICOM Bus.Intell.
File 369:New Scientist 1994-2004/Feb W5
         (c) 2004 Reed Business Information Ltd.
File 370:Science 1996-1999/Jul W3
         (c) 1999 AAAS
File 129:PHIND(Archival) 1980-2004/Mar W1
         (c) 2004 PJB Publications, Ltd.
File 130:PHIND(Daily & Current) 2004/Mar 11
         (c) 2004 PJB Publications,Ltd.
File 135:NewsRx Weekly Reports 1995-2004/Feb W5
         (c) 2004 NewsRx
File  98:General Sci Abs/Full-Text 1984-2004/Feb
         (c) 2004 The HW Wilson Co.
File  15:ABI/Inform(R) 1971-2004/Mar 11
         (c) 2004 ProQuest Info&Learning
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Set     Items   Description
S1      42735   VERTEBR???? OR INTERVERTEBR???? OR INTERSPINAL?? OR INTERS-
             PINOUS?? OR SPINE? ? OR SPINAL OR SPINOUS OR BACKBONE? ? OR B-
             ACK()BONE? ?
S2    1486575   BLOCK? ? OR BONEBLOCK? ? OR CHOCK? ? OR WEDGE? ? OR IMPLAN-
             T? ? OR INSERT? ? OR DOWEL? ? OR SPRAG? ? OR SWAGE? ? OR SHIM?
              ? OR SPACER? ? OR SPACING()ELEMENT? ?
S3    1894497   INSERT???? OR EMPLAC????? OR ADVANC????? OR INTRODUC????? -
             OR INFIX??? OR EMBED???? OR IMBED???? OR SANDWICH????
S4    2880615   PENETRAT???? OR INTERSPERS???? OR POSITION??? OR (CUT OR C-
             UTS OR CUTTING OR STICK??? OR PUT OR PUTS OR PUTTING)()IN
S5    2194869   SEPARAT???? OR DIVID??? OR DIVERG??? OR DETACH??? OR DISUN-
             IT??? OR DISPLAC??? OR DECOUPL??? OR DISJOIN??? OR DISCONNECT-
             ???
S6     192244   PARTITION??? OR SEGREGAT??? OR (CAM OR CAMS OR CAMMED OR C-
             AMMING OR SPREAD??? OR URGE? ? OR URGING)()APART
S7    2826818   ROTAT???? OR TWIRL??? OR TURN??? OR SPIN???? OR REVOLV??? -
             OR SCREW??? OR CIRCUMVOLV??? OR ORIENTAT???? OR GYRAT????
S8    1573403   REMOV???? OR WITHDRAW??? OR DISLODG??? OR EXTIRPAT???? OR -
             EVACUAT???? OR (TAKE? ? OR TAKING OR TOOK)()AWAY
S9    5444619   TWO OR TWIN OR DOUBLE OR SECOND OR BOTH OR PAIR OR 2ND
S10   2366801   PLURAL???? OR SEVERAL OR MULTITUDE OR MULTIPLE OR MULTI OR
             MANY OR ADDITIONAL OR NUMEROUS OR SPARE OR EXTRA OR MORE()THA-
             T()ONE
S11   4013287   METHOD? ?
S12   2945741   SYSTEM? ?
S13   2381827   PROCESS??
S14    196042   PROCEDURE? ?
S15    219522   TECHNIQUE? ?
S16    237714   IC=A61B?
S17      5552   S1 AND S2
S18      2956   S17 AND S11:S15
S19       303   S18 AND S11:S15(5N)S3:S4
S20       330   S18 AND S2(5N)S9:S10
S21        48   S19 AND S20
S22       214   S19:S20 AND S16
S23       585   S19:S22
S24        20   S23 AND S3:S4 AND S5:S6 AND S7 AND S8
S25        63   S21 OR S24
S26         5   S21 AND S24
S27        20   S24 OR S26
S28        20   IDPAT (sorted in duplicate/non-duplicate order)
? show files
File 347:JAPIO Nov 1976-2003/Nov(Updated 040308)
         (c) 2004 JPO & JAPIO
File 350:Derwent WPIX 1963-2004/UD,UM &UP=200416
         (c) 2004  THOMSON DERWENT
?
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28/3,K/15 (Item 15 from file: 350)
DIALOG(R)File 350:Derwent WPIX

012881534 **Image available**
WPI Acc No: 2000-053368/200004
Related WPI Acc No: 2000-053403; 2000-062577; 2000-161234; 2000-256314; 2000-465601; 2000-465647; 2000-475594; 2000-543652; 2000-656406; 2000-665184; 2000-665185; 2000-665186; 2001-327217; 2001-488078; 2001-637816; 2002-214238; 2002-214496; 2003-328171; 2003-370594
XRPX Acc No: N00-041539
Bone blocks inserting method **into patient's** intervertebral **space**
Patent Assignee: NUVASIVE INC (NUVA-N)
Inventor: MARINO J F; MCKINLEY J T; STONE C W; MARINO M J F; MCKINLEY J K
Number of Countries: 084 Number of Patents: 008
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
WO 9960837	A2	19991202	WO 99US11597	A	19990526	200004	B
AU 9942058	A	19991213	AU 9942058	A	19990526	200020	
US 6290724	B1	20010918	US 9886945	P	19980527	200157	
			US 98113651	P	19981223		
			US 99120663	P	19990219		
			US 99320161	A	19990526		
US 6312443	B1	20011106	US 98113651	P	19981223	200170	
			US 99467944	A	19991221		
KR 2001071658	A	20010731	KR 2000713959	A	20001208	200208	
US 6368325	B1	20020409	US 9886945	P	19980527	200227	
			US 98113651	P	19981223		
			US 99120663	P	19990219		
			US 99320081	A	19990526		
US 20020055745	A1	20020509	US 9886945	P	19980527	200235	
			US 98113651	P	19981223		
			US 99120663	P	19990219		
			US 99320081	A	19990526		
			US 200132121	A	20011221		
JP 2002529117	W	20020910	WO 99US12609	A	19990604	200274	
			JP 2000565788	A	19990604		

Priority Applications (No Type Date): US 99120663 P 19990219; US 9886945 P 19980527; US 98113651 P 19981223; US 99320161 A 19990526; US 99467944 A 19991221; US 9888863 A 19980609; US 99326740 A 19990604; US 99320081 A 19990526; US 200132121 A 20011221; US 9888663 P 19980609
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 9960837	A2	E	60	A61F-000/00	
Designated States (National): AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG UZ VN YU ZW					
Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW NL OA PT SD SE SL SZ UG ZW					
AU 9942058	A				Based on patent WO 9960837
US 6290724	B1			A61F-002/44	Provisional application US 9886945
					Provisional application US 98113651
					Provisional application US 99120663
US 6312443	B1			A61M-029/00	Provisional application US 98113651
KR 2001071658	A			A61B-006/08	
US 6368325	B1			A61F-002/46	Provisional application US 9886945
					Provisional application US 98113651
					Provisional application US 99120663
US 20020055745	A1			A61B-017/88	Provisional application US 9886945

Provisional application US 98113651
Provisional application US 99120663
Cont of application US 99320081
JP 2002529117 W 17 A61B-006/00 Based on patent WO 200010461

Bone blocks inserting method **into patient's** intervertebral **space**
Abstract (Basic):
... The bone **block** (10b) is supported in an **inserter** (20) which is **advanced** into the **intervertebral** space. After the **inserter** is received into the patient's **intervertebral** space, it is **rotated** approximately ninety degrees. Convexly curved outer camming surfaces on the **inserter** operate to **separate** the adjacent **vertebral** as the **inserter** is **rotated** .
... **Rotation** of the **inserter** by ninety degrees also operates to orient the bone **block** in a preferred **orientation** relative to the opposite **vertebral** surfaces. An INDEPENDENT CLAIM is also included for a **system** for **introducing** a bone **block** into the **intervertebral** space of a patient...

...For **inserting** a bone **block** into patient's **intervertebral** space...

...After the bone **block** is **rotated** into **position** , it supports the **spinal** load, thereby easing pressure on the **vertebral** disc and surrounding tissue. As such prior distraction of the adjacent **vertebrae** with dedicated instrumentation is substantially minimized. After the bone **block** is **rotated** into an anchored **position** between the adjacent **vertebrae** , the **inserter** is **withdrawn** from the **intervertebral** space leaving the bone **block** in a preferred **position** to promote bone fusion between the adjacent **vertebrae** .
...

...The figure shows the perspective view of bone **block** **inserter** .
...

...Bone **block** (10b...

... **Inserter** (20
...Title Terms: **BLOCK** ;
International Patent Class (Main): **A61B-006/00** ...

... **A61B-006/08** ...

... **A61B-017/88**

28/3,K/17 **(Item 17 from file: 350)**
DIALOG(R)File 350:Derwent WPIX

010011629 **Image available**
WPI Acc No: 1994-279341/199434
XRPX Acc No: N94-220123
Spinal **surgical stabilisation** method - **involves** inserting **distraction plug between** vertebrae **to urge them apart before locating drill tube guided in** position .
Patent Assignee: SPINE-TECH INC (SPIN-N); SULZER SPINE-TECH LTD (SULZ)
Inventor: KOHRS D W; KUSLICH S D
Number of Countries: 049 Number of Patents: 018
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week
WO 9417759	A1	19940818	WO 94US586	A	19940112	199434 B
AU 9460893	A	19940829	AU 9460893	A	19940112	199501
			WO 94US586	A	19940112	
EP 683651	A1	19951129	EP 94907232	A	19940112	199601
			WO 94US586	A	19940112	
US 5489307	A	19960206	US 9315863	A	19930210	199612
			US 94299807	A	19940901	
JP 8506501	W	19960716	JP 94518048	A	19940112	199650
			WO 94US586	A	19940112	
AU 9728772	A	19971002	AU 9460893	A	19940112	199747
			AU 9728772	A	19970721	
AU 683243	B	19971106	AU 9460893	A	19940112	199802
US 5700291	A	19971223	US 9315863	A	19930210	199806
			US 94299807	A	19940901	
			US 95488375	A	19950607	
US 5720748	A	19980224	US 9315863	A	19930210	199815
			US 94299807	A	19940901	
			US 95482025	A	19950607	
AU 695006	B	19980806	AU 9460893	A	19940112	199843
			AU 9728772	A	19970721	
US 5899908	A	19990504	US 9315863	A	19930210	199925
			US 94299807	A	19940901	
			US 95482025	A	19950607	
			US 96752818	A	19961121	
			US 97901950	A	19970729	
US 5928242	A	19990727	US 9315863	A	19930210	199936
			US 94299807	A	19940901	
			US 95488375	A	19950607	
			US 97891276	A	19970710	
US 5947971	A	19990907	US 9315863	A	19930210	199943
			US 94299807	A	19940901	
			US 95482025	A	19950607	
			US 96752818	A	19961121	
EP 683651	B1	19990929	EP 94907232	A	19940112	199945
			WO 94US586	A	19940112	
DE 69420947	E	19991104	DE 620947	A	19940112	199953
			EP 94907232	A	19940112	
			WO 94US586	A	19940112	
ES 2141217	T3	20000316	EP 94907232	A	19940112	200021
MX 196241	B	20000502	MX 94846	A	19940202	200129
US 6599320	B1	20030729	US 9315863	A	19930210	200354
			US 94299807	A	19940901	
			US 95482025	A	19950607	
			US 96752818	A	19961121	
			US 97902746	A	19970729	

Priority Applications (No Type Date): US 9315863 A 19930210; US 94299807 A 19940901; US 95488375 A 19950607; US 95482025 A 19950607; US 96752818 A 19961121; US 97901950 A 19970729; US 97891276 A 19970710; US 97902746 A 19970729; US 99369614 A 19990806

Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
WO 9417759	A1	E	59	A61F-002/44	
Designated States (National): AT AU BB BG BR BY CA CH CN CZ DE DK ES FI GB HU JP KP KR KZ LK LU LV MG MN MW NL NO NZ PL PT RO RU SD SE SK UA UZ VN					
Designated States (Regional): AT BE CH DE DK ES FR GB GR IE IT LU MC NL OA PT SE					
AU 9460893	A			A61F-002/44	Based on patent WO 9417759
EP 683651	A1	E	14	A61F-002/44	Based on patent WO 9417759
Designated States (Regional): AT BE CH DE DK ES FR GB GR IE IT LI LU MC NL PT SE					
US 5489307	A		29	A61F-002/44	Cont of application US 9315863
JP 8506501	W		83	A61F-002/44	Based on patent WO 9417759
AU 9728772	A			A61F-002/44	Div ex application AU 9460893
AU 683243	B			A61F-002/44	Previous Publ. patent AU 9460893 Based on patent WO 9417759
US 5700291	A		28	A61F-002/44	Cont of application US 9315863 Cont of application US 94299807 Cont of patent US 5489307
US 5720748	A		28	A61B-017/17	Div ex application US 9315863 Div ex application US 94299807 Div ex patent US 5489307
AU 695006	B			A61F-002/44	Div ex application AU 9460893 Previous Publ. patent AU 9728772
US 5899908	A			A61B-017/90	Cont of application US 9315863 Div ex application US 94299807 Cont of application US 95482025 Div ex application US 96752818 Div ex patent US 5489307 Cont of patent US 5720748
US 5928242	A			A61B-017/90	Cont of application US 9315863 Cont of application US 94299807 Cont of application US 95488375 Cont of patent US 5489307 Cont of patent US 5700291
US 5947971	A			A61B-017/17	Cont of application US 9315863 Div ex application US 94299807 Cont of application US 95482025 Div ex patent US 5489307 Cont of patent US 5720748
EP 683651	B1	E		A61F-002/44	Based on patent WO 9417759
Designated States (Regional): AT BE CH DE DK ES FR GB GR IE IT LI LU MC NL PT SE					
DE 69420947	E			A61F-002/44	Based on patent EP 683651 Based on patent WO 9417759
ES 2141217	T3			A61F-002/44	Based on patent EP 683651
MX 196241	B			A61F-002/044	
US 6599320	B1			A61F-002/46	Cont of application US 9315863 Div ex application US 94299807 Cont of application US 95482025 Div ex application US 96752818 Cont of application US 97902746 Div ex patent US 5489307 Cont of patent US 5720748

Div ex patent US 5947971

Spinal **surgical stabilisation** method - ...

...**involves** inserting **distraction plug between** vertebrae **to urge them apart before locating drill tube guided in** position .

...Abstract (Basic): The **method** comprises **inserting** a distraction **spacer** into the disc space at a desired first **implant** location on the first side, with the first distraction **spacer** sized to urge the first and second **vertebrae** apart upon the **insertion** . The **method** then involves placing a guide at the second side, with the guide adapted to direct...
...an axis parallel to and equidistant between opposing end plates of the first and second **vertebrae** .
...

...The **method** comprises forming a **second implant** bore at the desired **second implant** location by **removing** bone material from the first and second **vertebrae** and by **removing** disc material at the **second implant** location, with the **second implant** bore sized to receive the **second implant** . It then comprises implanting the **implant** into the **second implant** bore...

...USE - A surgical **method** for implanting at least **two spinal** fusion **implants** into a disc space of disc material **separating** first and second **vertebrae** . The disc space and **vertebrae** are divisible into first and second sides **separated** by a sagittal plane
...Abstract (Equivalent): The **method** comprises **inserting** a distraction **spacer** into the disc space at a desired first **implant** location on the first side, with the first distraction **spacer** sized to urge the first and second **vertebrae** apart upon the **insertion** . The **method** then involves placing a guide at the second side, with the guide adapted to direct...
...an axis parallel to and equidistant between opposing end plates of the first and second **vertebrae** .
...

...The **method** comprises forming a **second implant** bore at the desired second implant location by **removing** bone material from the first and second **vertebrae** and by **removing** disc material at the **second implant** location, with the **second implant** bore sized to receive the **second implant** . It then comprises implanting the **implant** into the **second implant** bore...

...USE - A surgical **method** for implanting at least **two spinal** fusion **implants** into a disc space of disc material **separating** first and second **vertebrae** . The disc space and **vertebrae** are divisible into first and second sides **separated** by a sagittal plane...

...The **method** comprises **inserting** a distraction **spacer** into the disc space at a desired first **implant** location on the first side, with the first distraction **spacer** sized to urge the first and second **vertebrae** apart upon the **insertion** . The **method** then involves placing a guide at the second side, with the guide adapted to direct...
...an axis parallel to and equidistant between opposing end plates of the first and second **vertebrae** .
...

...The **method** comprises forming a **second implant** bore at the desired **second implant** location by **removing** bone material from the first and second **vertebrae** and by **removing** disc material at the **second implant** location, with the **second implant** bore sized to receive the **second implant** . It then comprises implanting the **implant** into the **second implant** bore...

...USE - A surgical **method** for implanting at least **two spinal** fusion **implants** into a disc space of disc material **separating** first and second **vertebrae** . The disc space and **vertebrae** are divisible into first and second sides **separated** by a sagittal plane...

...A surgical **method** for implanting at least **two spinal** fusion **implants** into a disc space of disc material **separating** a first and second **vertebrae** , said disc space and first and second **vertebrae** divisible into first and second sides **separated** by a sagittal plane, said **method** comprising the steps of...

...a) **inserting** a rigid distraction **spacer** into said disc space at a desired first **implant** location on said first side with said first distraction **spacer** sized for external surfaces of said first distraction **spacer** to act against first and **second** end plates of said first and second **vertebrae** , respectively, to urge said first and second **vertebrae** apart upon said **insertion** , said **spacer inserted** for said **spacer** to be recessed within said space so as not to substantially protrude beyond said space...

...b) placing a guide at said second side while maintaining distraction at said first **implant** location with said distraction **spacer** and with said guide adapted to direct tools axially through an axis parallel to and equidistant between opposing end plates of said first and second **vertebrae** ;

(...

...c) forming a **second implant** bore at a desired **second implant** location by **removing** bone material from said first and second **vertebrae** and by **removing** disc material at said **second implant** location with said **second implant** bore sized to receive said **second implant** , said forming of said **second** bore utilizing at least a first boring tool guided by said guide...

...d) implanting said **second implant** into said **second implant** bore ...

...e) **removing** first distraction **spacer** and applying a guide to said first side...

...f) forming a first **implant** bore at said desired first location by **removing** bone material from said first and second **vertebrae** and by **removing** disc material at said first **implant** location with said first bore sized to receive said first **implant** , said forming of said first bore utilizing at least a first boring tool guided by...

...g) implanting said first **implant** into said first **implant** bore

Title Terms: **SPINE** ;

International Patent Class (Main): **A61B-017/17** ...

... **A61B-017/90**

International Patent Class (Additional): **A61B-017/16** ...

... **A61B-017/56** ...

28/3,K/19 (Item 19 from file: 350)
DIALOG(R)File 350:Derwent WPIX

007929731
WPI Acc No: 1989-194843/198927
XRPX Acc No: N89-148944
Surgical locking implant **for** spine **- comprises elongate** block **for** insertion **between adjacent** vertebrae **, with cut-outs to allow passage of** spinal **apophyses**
Patent Assignee: BREARD F H (BREA-I)
Inventor: BREARD F H
Number of Countries: 015 Number of Patents: 007
Patent Family:

Patent No	Kind	Date	Applicat No	Kind	Date	Week	
FR 2623085	A	19890519	FR 8715783	A	19871116	198927	B
EP 392124	A	19901017	EP 89401040	A	19890414	199042	N
US 5011484	A	19910430	US 89418661	A	19891010	199119	N
CA 1315044	C	19930330	CA 613587	A	19890927	199318	N
EP 392124	B1	19930616	EP 89401040	A	19890414	199324	N
DE 68907202	E	19930722	DE 607202	A	19890414	199330	N
			EP 89401040	A	19890414		
ES 2043053	T3	19931216	EP 89401040	A	19890414	199403	N

Priority Applications (No Type Date): FR 8715783 A 19871116; CA 613587 A 19890927; DE 607202 A 19890414; EP 89401040 A 19890414; US 89418661 A 19891010
Patent Details:

Patent No	Kind	Lan	Pg	Main IPC	Filing Notes
FR 2623085	A		8		
EP 392124	A				
Designated States (Regional): AT BE CH DE ES GB GR IT LI LU NL SE					
CA 1315044	C	F		A61B-017/56	
EP 392124	B1	F	5	A61F-005/02	
Designated States (Regional): AT BE CH DE ES GB GR IT LI LU NL SE					
DE 68907202	E			A61F-005/02	Based on patent EP 392124
ES 2043053	T3			A61F-005/02	Based on patent EP 392124

Surgical locking implant **for** spine **- ...**

...comprises elongate block **for** insertion **between adjacent** vertebrae **, with cut-outs to allow passage of** spinal **apophyses**

...Abstract (Basic): The **implant** consists of a wedging **block** (1a) which is dimensioned and shaped for longitudinal **insertion** between the **spinal** apophyses (A) of at least **two** adjacent **vertebrae** (V). The **block** includes retainers (21) to secure the **vertebrae** at a pre-determined spacing...

...The **block** includes at least one longitudinal hole (16) of a size and **position** to allow the passage of one apophyses with a small amount of vertical play. Longitudinal notches in the ends of the **block** are also sized to accommodate adjacent apophyses...

...USE - Treatment of **spinal** nerve disorders, e.g. sciatica.
...Abstract (Equivalent): A surgical **implant** intended to prevent physical contact between **vertebrae** during flexion of the **spinal** column, such **implant** comprising an **intervertebral spacer** (1, 1a) to be **inserted** between the **processes** (A) of at least two neighbouring **vertebrae** (V) in addition to a continuous artificial ligament (L),

unattached to the **spacer** component and intended to keep it in **position** in relation to the **processes** , and allowing upward deflection of the latter, the **spacer** presenting on one and/or the other of its opposite faces a groove (2, 3) intended to receive and to guide the **spines** of the respective **vertebrae** (A) and of larger dimensions than the latter...

...Abstract (Equivalent): The **implant** consists of an **insert** (1) shaped and dimensioned so that it can be **inserted** in its longitudinal direction between the **vertebral spines** (A) of at least **two** successive **vertebrae** (V). The **insert** comprises, or is associated with, retainers (L) designed to hold it in place on the **vertebrae** , at the same time permitting the mutual **separation** of the latter...

...Advantageously, the **insert** (1) has longitudinal grooves (2, 3) dimensioned to receive with a certain amount of play a corresponding **vertebral spine** (A). The retainers are constituted by a ligament (L) passing through transverse pierced holes, preferably two inclined, cross pierces holes (8), in the **insert** , and interlacing around the **vertebral spines** (A). Utilisation to **remove** painful complaints of the **spinal** nerves, in particular sciatica...

...USE - A surgical **implant** designed to prevent mutual contact between **vertebrae** during flexions of the **vertebral** column. (5pp)

...Title Terms: **IMPLANT** ;

International Patent Class (Main): **A61B-017/56** ...